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PART 280—FASTENER QUALITY

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AUTHORITY: Sec. 13 of the Fastener Quality Act (Pub.L. 101–592, as amended by Pub. L. 104–113).

SOURCE: 61 FR 50558, Sept. 26, 1996, unless otherwise noted.

Subpart A—General

§ 280.1 Purpose/description of rule.

The Fastener Quality Act (the Act) (Pub.L. 101–592, as amended by Pub. L. 104–113) is intended to protect the public safety, to deter the introduction of nonconforming fasteners into commerce, to improve the ability to trace fasteners covered by the Act, and generate greater assurance that fasteners meet stated specifications. The Act:

(a) Requires that certain fasteners which are sold in commerce conform to the specifications to which they are represented to be manufactured,

(b) Provides for accreditation of laboratories engaged in fastener testing; and

(c) Requires inspection, testing and certification, in accordance with standardized methods, of fasteners covered by the Act.

§ 280.2 Definitions.

Unless the context requires otherwise or unless specifically stated the terms in this part have the meanings prescribed in the statute. In addition the following definitions apply.

Accreditation means laboratory accreditation.

Accreditation body refers to the National Voluntary Laboratory Accreditation Program and those private entities currently approved by NIST under subpart D of this part and those foreign governments or organizations currently recognized by NIST under subpart E of this part.

Accreditation criteria means a set of requirements used by an accreditation body which a laboratory must meet to be accredited.

The Act means the Fastener Quality Act (Pub.L. 101–592, as amended by Pub.L. 104–113).

Alter means to alter by through hardening; by electroplating of fasteners; or by machining.

Alteror means a person who owns a fastener and causes it to be altered.

Approved signatory is an individual employed by a laboratory accredited under the Act and these regulations who is recognized by an accreditation body as competent to sign accredited laboratory test reports.

Bureau of Export Administration or (*BXA*) means the Bureau of Export Administration of the United States Department of Commerce, including the Office of Export Enforcement.

Certificate of accreditation is a document issued by an accreditation body to a laboratory that has met the criteria and conditions of accreditation. The certificate, together with the assigned code number, and scope of accreditation issued by the accreditation body may be used as proof of accredited status.

Commingling means the mixing of fasteners from different lots in the same container.

Commissioner means the Commissioner of Patents and Trademarks.

Consensus standards organization means the American Society for Testing and Materials (ASTM), American National Standards Institute (ANSI), American Society of Mechanical Engineers (ASME), Society of Automotive Engineers (SAE), or any other consensus standards setting organization (domestic or foreign) determined by the

Secretary to have comparable knowledge, expertise, and concern for the health and safety in the field for which such organization purports to set standards.

Container means any package of fasteners traded in commerce.

Date of manufacture means that date upon which the initial conversion of material into a fastener takes place.

Director means the Director of the National Institute of Standards and Technology (NIST).

Fastener means any screw, nut, bolt or stud, washer or other item included within the definition for fastener contained in section 3(5) of the Fastener Quality Act. The term ''fastener'' does not include a screw, nut, bolt, or stud:

(1) That is produced and marked as ASTM A307 Grade A;

(2) That is produced in accordance with ASTM F432; or

(3) That is held out as being produced to other than the provisions of standards and specifications published by a consensus standards organization, or a government agency.

A screw, nut, bolt, stud or washer held out as being produced according to requirements of a document other than a document published by a consensus standards organization is a fastener within the meaning of the Act and this part if that document incorporates or references (directly or indirectly) standards and specifications published by a consensus standards organization or government agency for purposes of delineating performance or materials characteristics of the fastener.

Fastener insignia register means the register established at the U.S. Patent and Trademark Office for the recordal of fastener insignia to identify the manufacturer or private label distributor.

Fastener set means a collection of small quantities of products, including fasteners, of varying sizes, collected together and sold as a package.

Grade or property class identification marking means any symbol appearing on a fastener purporting to indicate that the fastener's base material, strength properties, or performance capabilities conform to a specific standard of a consensus standards organization or government agency. A raw material mark is not considered as a grade identification mark for purposes of these regulations unless this mark is required by the fastener standards and specifications to identify specific conformance.

Importer means a person located within the United States who contracts for the initial purchase of fasteners manufactured outside the United States for resale or such person's use within the United States.

Laboratory accreditation is the formal recognition that a testing laboratory is competent to carry out specific test(s) or specific type(s) of tests.

Laboratory accreditation body means a legal or administrative entity that accredits laboratories.

Laboratory assessment means the on-site examination of a testing laboratory to evaluate its compliance with specified criteria.

Laboratory test report means a report prepared by an accredited laboratory in accord with § 280.6.

Lot means a quantity of fasteners of one part number fabricated by the same production process from the same coil or heat number of metal as provided by the metal manufacturer and submitted for inspection and testing at one time.

Lot number means a number assigned by a manufacturer to the lot.

Lot-specific identification information means information applicable to a fastener consisting of, at a minimum:

(1) The part number (or a part description if there is no applicable part number),

(2) The identity of the manufacturer, and

(3) The lot number.

Lot traceability means the recording and maintenance of lot-specific identification information sufficient to trace fasteners from a single lot throughout:

(1) The manufacturer's fabrication or alteration process,

(2) All inspection and testing operations, and

(3) The subsequent chain of distribution in commerce.

Manufacturer means a person who fabricates fasteners, who significantly alters fasteners, or who alters any item so that it becomes a fastener.

NIST means the National Institute of Standards and Technology, U.S. Department of Commerce.

NVLAP means the National Voluntary Laboratory Accreditation Program operated by the National Institute of Standards and Technology.

Original laboratory testing report means a laboratory testing report which is originally signed by an approved signatory or is a copy thereof, certified by the laboratory that conducted the test.

Person means any individual, partnership, limited partnership or corporate entity and/or a representative, agent or designee.

Private label distributor means a person who contracts with a manufacturer for the fabrication of fasteners bearing the distributor's distinguishing insignia.

Product includes any type or category of manufactured goods, constructions, installations, or natural or processed materials.

Proficiency testing means the determination of laboratory testing performance by means of comparing and evaluating tests on the same or similar items or materials in accordance with predetermined conditions.

Scope of accreditation is a document issued by an accreditation body to an accredited laboratory which lists the test methods, standards or specifications for which the laboratory is accredited.

Secretary means the Secretary of Commerce.

Significantly alter means to alter in a manner which could weaken or otherwise materially affect the performance or capabilities of the fastener as it was originally manufactured, grade or property class marked, tested, or represented. The term does not include the application of adhesives or sealants, locking elements, provisions for lock wires, coatings and platings of parts having a specified Rockwell C hardness of less than 32, or cutting off of fasteners. The cutting of finished threaded rods, bars or studs to produce individual smaller length threaded studs for resale is not a significant alteration. However, cut threaded studs, rods, and bars offered for sale shall be individually marked with the grade or property class identification marking appearing on or accompanying the original threaded studs, rods, and bars from which the fasteners were cut.

Standards and specifications means the provisions of a document published by a consensus standards organization, or a government agency.

Tamper-resistant system means the use of special paper or embossing stamps or other controls which discourage, prevent or minimize alteration of test reports subsequent to manufacturing, inspection and testing.

Testing laboratory is a laboratory which measures, examines, tests, calibrates or otherwise determines the characteristics or performance of products.

Through-harden means heating above the transformation temperature followed by quenching and tempering for the purpose of achieving a uniform hardness.

Traceability of measurements means a documented chain of comparisons connecting the accuracy of a measuring instrument to other measuring instruments of higher accuracy and, ultimately, to a primary standard.

§ 280.3 Relationship to State laws.

Nothing in the Act or these regulations shall be construed to preempt any rights or causes of action that any buyer may have with respect to any seller of fasteners under the law of any State, except to the extent that the provisions of the Act or these regulations are in conflict with such State law.

§ 280.4 Commingling of fasteners.

(a) No manufacturer, importer, or private label distributor may commingle fasteners of the same type, grade, and dimension from different lots in the same container; except that such manufacturer, importer, or private label distributor may commingle fasteners of the same type, grade, and dimension from not more than two tested and certified lots in the same container during repackaging and plating operations: Provided, that any container which contains the fasteners from two lots shall be conspicuously marked with the lot identification numbers of both lots.

(b) Fastener distributors, and persons who purchase fasteners for sale at wholesale or retail, may commingle fasteners of the same type, grade, and dimension from different lots in the same container.

§280.5 Certification of fasteners.

(a) No fastener shall be offered for sale or sold in commerce unless it is part of a lot which has been inspected, tested, and certified in accordance with Section 5 of the Act and this part, and found to conform to the standards and specifications to which the manufacturer represents it has been manufactured.

(b)(1) The requirements of paragraph (a) of this section shall not apply to fasteners which are part of a lot of 50 fasteners or less if within 10 working days after delivery of such fasteners, or as soon as practicable thereafter—

(i) Inspection, testing, and certification as provided in subsections 5 (b), (c), and (d) of the Act and this part is carried out; and

(ii) Written notice detailing the results of such inspection, testing, and certification is sent:

(A) To all purchasers of such fasteners, except retail sellers and retail consumers, and

(B) To any retail seller or retail consumer who, prior to delivery, requests such written notice.

(2) If a fastener is sold under paragraph (b) of this section, each purchaser of such fastener, except for retail sellers and retail consumers unless such retail sellers and retail consumers request such notice in advance, shall be provided, contemporaneously with each sale and delivery, written notice stating that such fastener has not yet been inspected, tested, and certified as required by the Act and this part.

(c) Each manufacturer, importer, private label distributor, or alteror who significantly alters any fastener shall keep on file and make available for inspection in accordance with the record-keeping requirements of §280.7 an original laboratory testing report described in section 5(c) of the Act and §280.6 of this part and a manufacturer's certificate of conformance for each lot of fasteners subject to the Act and this part which that manufacturer, importer, private label distributor, or alteror who significantly alters any fastener offers for sale or sells in commerce. Such certificate shall, as a minimum, include: Fastener description information contained in §280.6(a)(4) of this part; the date of issue and serial number of the laboratory testing report; and a statement certifying that the fasteners have been manufactured according to the requirements of the applicable standards and specifications and found to conform with its requirements. The requirements of this paragraph shall not apply to an alteror who significantly alters fasteners and who delivers to the purchaser the written statement provided for by §280.11(a)(3) of this part.

§280.6 Laboratory test reports.

(a) When performing tests for which they are accredited under this part, each laboratory accredited under subparts C, D, or E of this part and currently listed in the Accredited Laboratory List shall issue test reports of its work which accurately, clearly, and unambiguously present the test conditions, test set-up, test results, and all information required by this section. All reports must be in English or be translated into English, must be signed by an approved signatory, must be protected by a tamper resistant system, and contain the following information:

(1) Name and address of the laboratory;

(2) Unique identification of the test report including date of issue and serial number, or other appropriate means;

(3) Name and address of client;

(4) Fastener Description, including:

(i) Manufacturer (name and address);

(ii) Product family (screw, nut, bolt, washer, or stud), drive and/or head configurations as applicable;

(iii) Date of manufacture;

(iv) Head markings (describe or draw manufacturer's recorded insignia and grade identification or property class symbols);

(v) Nominal dimensions (diameter; length of bolt, screw or stud; thickness of load bearing washer); thread form and class of fit;

(vi) Product standards and specifications related to the laboratory in writing by the manufacturer, importer or distributor;

(vii) Lot number;

(viii) Specification and grade of material;

(ix) Coating material and standard and specification as applicable;

(5) Sampling information:

(i) Standards and specifications or reference for sampling scheme;

(ii) Production lot size and the number sampled and tested;

(iii) Name and affiliation of person performing the lot sampling;

(6) Test results:

(i) Actual tests required by the standard and specification;

(ii) Test results for each sample;

(iii) All deviations from the test method;

(iv) All other items required on test reports according to the test method;

(v) Where the report contains results of tests performed by sub-contractors, these results shall be clearly identified along with the name of the laboratory and accreditation information listed in paragraph (a)(10) of this section.

(vi) A statement that the samples tested either *conform* or *do not conform* to the fastener standards and specifications or standards and identification of any nonconformance, except as provided for in §§ 280.13 and 280.14;

(7) A statement that the report must not be reproduced except in full;

(8) A statement to the effect that the test report relates only to the item(s) tested;

(9) Name, title and signature of approved signatory accepting technical responsibility for the tests and test report;

(10) The name of the body which accredited the laboratory for the specific tests performed which are the subject of the report, and code number assigned to the laboratory by the accreditation body, and the expiration of accreditation.

(b) For alternative chemical tests carried out under § 280.15 of this part, each laboratory accredited under subparts C, D, or E of this part and currently listed in the Accredited Laboratory List shall provide to the fastener manufacturer, either directly or through the metal manufacturer, a written inspection and testing report containing all required information. All reports must be in English or be translated into English, must be signed by an approved signatory, must be protected by a tamper resistant system, and contain the following information:

(1) Name and address of the laboratory;

(2) Unique identification of the test report including date of issue and serial number or other appropriate means.

(3) Name and address of client;

(4) Coil or heat number of metal being tested;

(5) Test results:

(i) Actual tests required by the standards and specifications;

(ii) Test results for each sample;

(iii) All deviations from the test method;

(iv) All other items required on test reports according to the test method;

(v) Where the report contains results of tests performed by sub-contractors, these results shall be clearly identified along with the name of the laboratory and accreditation information listed in paragraph (b)(9) of this section.

(vi) A statement that the samples tested either *conform* or *do not conform* to the metal standards and specifications and identification of any nonconformance;

(6) A statement that the report must not be reproduced except in full;

(7) A statement to the effect that the test report relates only to the item(s) tested;

(8) Name, title and signature of approved signatory accepting technical responsibility for the tests and test report;

(9) The name of the body which accredited the laboratory for the specific tests performed which are the subject of the report, and code number assigned to the laboratory by the accreditation body, and the expiration of accreditation.

(c) The laboratory shall issue corrections or additions to a test report only by a further document suitably marked, e.g. ''Supplement to test report serial number * * *'' This document must specify which test result is in question, the content of the result,

the explanation of the result, and the reason for acceptance of the result.

§ 280.7 Recordkeeping requirements.

(a) Each laboratory accredited under subparts C, D, or E of this part shall retain for 5 years after the performance of a test all records pertaining to that test concerning the inspection and testing, and certification, of fasteners under the Act and these regulations. The final test report or the test records maintained by the laboratory shall contain sufficient information to permit the test to be repeated at a later time if a retest is necessary. The laboratory shall maintain the test report and a record of all original observations, calculations, and derived data. The records shall include the identity of personnel involved in sample preparation and testing. Procedures for storage and retrieval of records must be documented and maintained in the laboratory's quality manual.

(b) Manufacturers, importers, private label distributors, and persons who significantly alter fasteners shall retain for 5 years after the performance of a test all records pertaining to that test concerning the inspection and testing, and certification, of fasteners under the Act and these regulations.

(c) Original records required. Persons required to keep records under this part must maintain the original records in the form in which that person receives or creates them unless that person meets all of the conditions of paragraph (d) of this section relating to reproduction of records. Original laboratory test reports described in §§ 280.5, 280.6, 280.13 and 280.15(b) of this part must be kept.

(d) Reproduction of original records. A person required to keep records under this part may maintain reproductions of documents other than laboratory test reports instead of the original records using any photographic, photostatic, miniature photographic, micrographic, automated archival storage, or other process that completely, accurately, legibly and durably reproduces the original records (whether on paper, microfilm, or through electronic digital storage techniques). The process must meet all of the requirements of paragraphs (d)(1) through (d)(9) of this section.

(1) The system must be capable of reproducing all records on paper.

(2) The system must record and be able to reproduce all marks, information, and other characteristics of the original record, including both obverse and reverse sides of paper documents in legible form.

(3) When displayed on a viewer, monitor, or reproduced on paper, the records must exhibit a high degree of legibility and readability. (For purposes of this section, legible and legibility mean the quality of a letter or numeral that enable the observer to identify it positively and quickly to the exclusion of all other letters or numerals. Readable and readability mean the quality of a group of letters or numerals being recognized as complete words or numbers.)

(4) The system must preserve the initial image (including both obverse and reverse sides of paper documents) and record all changes, who made them and when they were made. This information must be stored in such a manner that none of it may be altered once it is initially recorded.

(5) The regulated person must establish written procedures to identify the individuals who are responsible for the operation, use and maintenance of the system.

(6) The regulated person must establish written procedures for inspection and quality assurance of records in the system and document the implementation of those procedures.

(7) The system must be complete and contain all records required to be kept by this part or the regulated person must provide a method for correlating, identifying and locating records relating to the same transaction(s) that are kept in other record keeping systems.

(8) The regulated person must keep a record of where, when, by whom, and on what equipment the records and other information were entered into the system.

(9) Upon request by the Bureau of Export Administration or NIST, the regulated person must furnish, at the examination site, the records, the equipment and, if necessary, knowledgeable

personnel for locating, reading, and reproducing any record in the system.

(e) Destruction or disposal of records. If the Bureau of Export Administration, NIST or any other government agency makes a formal or informal request for any record or records, such record or records may not be destroyed or disposed of without the written authorization of the agency concerned. This prohibition applies even if such records have been retained for a period of time exceeding that required by paragraphs (a) or (b) of this section.

(f) All persons required to keep records by this part must furnish those records when requested to do so by an employee of the Bureau of Export Administration or NIST.

§ 280.8 Ownership of laboratories by manufacturers.

(a) If the Director finds that, as to a specific type of fastener, and as to a specific type of inspection or testing, a ban on manufacturer ownership or affiliation with a laboratory performing tests under the Act and these regulations would increase the protection of health and safety of the public or industrial workers, the Director may impose such a ban.

(b) Before imposing a ban under paragraph (a) of this section, the Director shall provide advance notice and the opportunity for public comment.

§ 280.9 Subcontracting of testing.

(a) Whenever a laboratory accredited under subparts C, D, or E of this part issues a test report under the Act and this part, it is implied that the report reflects work performed, and results obtained, by the personnel, equipment, and procedures of that laboratory. However, in some cases a laboratory may require the use of another facility due to equipment failure, need for specialized equipment, work overload, or to perform tests outside the laboratory's own scope of accreditation.

(b) Whenever a laboratory accredited under subparts C, D, or E of this part subcontracts to another laboratory for the performance of any test or portion of a test it must:

(1) Place the work with another laboratory accredited under either subpart C, D, or E of this part;

(2) Inform the client, before the fact, that subcontracting will be necessary; and

(3) Clearly identify in its records, and in the report to the client, specifically which test method(s) or portions of a test method(s) were performed by the accredited laboratory and which were performed by the subcontractor.

§ 280.10 Sampling.

In the event that the standard or specification to which a manufacturer represents the fasteners in a particular sample to have been manufactured does not provide for the size, selection or integrity of the sample to be inspected and tested, the sample shall be determined in accordance with ASME/ANSI B18.18.2M, *Inspection and Quality Assurance For High-Volume Machine Assembly Fasteners;* ASME/ANSI B18.18.3M, *Inspection and Quality Assurance for Special Purpose Fasteners;* or ASME/ANSI B18.18.4M, *Inspection and Quality Assurance for Highly Specialized Engineering Applications—Fasteners,* as appropriate.

§ 280.11 Significant alterations of fasteners.

(a) Any alteror who significantly alters a fastener so that it no longer conforms to the description in the relevant test report issued under section 5(c) of the Act or this part, and who thereafter offers for sale or sells such significantly altered fastener, shall:

(1) Assign a new lot number;

(2) Apply his or her registered insignia to the significantly altered fastener if the standards and specifications to which the fastener was originally manufactured required the fastener to bear a raised or depressed insignia identifying its manufacturer or private label distributor; and

(3) Be treated as a manufacturer for the purposes of the Act and this part, and shall cause the fastener to be inspected and tested as required by section 5 of the Act and by this part unless the significantly altered fastener is delivered to a purchaser accompanied by a written statement noting the original lot number and the new lot number assigned by the alteror, disclosing the subsequent alteration, and

warning that such alteration may affect the dimensional or physical characteristics of the fastener.

(b) If the significant alteration is only electroplating of fasteners having a specified Rockwell C hardness of 32 or above, the requirements set forth in paragraphs (a)(2) and (a)(3) of this section shall not apply, but the alteror shall assign a new lot number as set forth in paragraph (a)(1) of this section and shall test the electroplated fasteners as required by the plating standards and specifications.

(c) Any person who knowingly sells a significantly altered fastener as described in paragraph (a) of this section, and who did not alter such fastener, shall provide to the purchaser a copy of the statement required by paragraph (a)(3) of this section; unless the significant alteration is only electroplating of the fastener, as described in paragraph (b) of this section.

(d) If the alteration is not a significant alteration, the requirements set forth in paragraph (a) of this section shall not apply, and the only testing requirements which apply are those required by the standards and specifications to which the alteration is performed. If the alteration involves cutting of threaded studs, rods, or bars into studs, these cut fasteners must be marked with the grade or property class identification marking appearing on the original threaded studs, rods, and bars.

§280.12 Applicability.

(a) The requirements of the Fastener Quality Act and this part shall be applicable only to fasteners manufactured on or after May 27, 1997.

(b) Metal manufactured prior to May 27, 1997 may not be used to manufacture fasteners subject to the Act and this part, unless the metal has been tested for chemistry pursuant to §280.15 of this part by a laboratory accredited under the Act and this part and the chemical characteristics of the metal conform to those required by the standards and specifications.

(c) Nothing in the Act and this part prohibits selling finished fasteners manufactured prior to May 27, 1997 or representing that such fasteners meet standards and specifications of a consensus standards organization or a government agency. Fasteners manufactured prior to May 27, 1997 may not be represented as being in conformance with the Act or this part.

§280.13 Imports of fasteners.

(a) Except as provided in paragraph (b) of this section, it shall be unlawful for any person to sell to an importer, and for any importer to purchase any shipment of fasteners or fastener sets manufactured outside the United States unless such shipment to an importer is accompanied by a manufacturer's certificate of conformance, an original laboratory testing report with respect to each lot from which the fasteners are taken, and any other relevant lot identification information.

(b) The requirement that delivery of fasteners to any importer must be accompanied by an original laboratory testing report shall not apply:

(1) In the case of fasteners imported into the United States as products manufactured within a nation which is party to a congressionally approved free trade agreement with the United States that is in effect, provided that the Director has published in the FEDERAL REGISTER a certification that satisfactory arrangements have been reached by which purchasers within the United States can readily gain access to an original laboratory test report for such fasteners; or,

(2) In the case of fasteners imported into the United States as Canadian-origin products under the United States-Canada Automobile Pact for use as original equipment in the manufacture of motor vehicles.

§280.14 Option for importers and private label distributors.

(a) Notwithstanding the provisions of §280.13 of this part, delivery of a lot, or portion of a lot, of fasteners may be made by a manufacturer to an importer or private label distributor without the required original copy of the laboratory testing report if—

(1) The manufacturer provides to the importer or private label distributor a certificate which, as a minimum, includes fastener description information contained in §280.6(a)(4), and a statement by the manufacturer certifying

that the fasteners have been manufactured according to the requirements of the applicable standard or specification, but have not been tested by a laboratory accredited in accordance with section 6 of the Act; and

(2) The importer or private label distributor assumes responsibility in writing for the inspection and testing of such lot or portion by a laboratory accredited in accordance with the procedures set out in this Part.

(b) If the importer or private label distributor assumes the responsibility in writing for the inspection and testing of such lot or portion, the provisions of section 5(a), (b) and (c) of the Act shall apply to the importer or private label distributor in the same manner and to the same extent as to a manufacturer; except that the importer or private label distributor shall provide to the testing laboratory the certificate described under paragraph (a)(1) of this section.

§ 280.15 Alternative procedure for chemical characteristics.

Notwithstanding any other provision of this regulation, a manufacturer shall be deemed to have demonstrated that the chemical characteristics of a lot conform to the standards and specifications to which the manufacturer represents such lot has been manufactured if the following requirements are met:

(a) The coil or heat number of metal from which such lot was fabricated has been inspected and tested with respect to its chemical characteristics by a laboratory accredited in accordance with the Act and these regulations;

(b) Such laboratory has provided to the manufacturer, either directly or through the metal manufacturer, a written inspection and testing report, prepared in accordance with § 280.6 of this part, listing the chemical characteristics of such coil or heat number;

(c) The report described in paragraph (b) of this section indicates that the chemical characteristics of such coil or heat number conform to those required by the standards and specifications to which the manufacturer represents such lot has been manufactured; and,

(d) The manufacturer demonstrates that such lot has been fabricated from the coil or heat number of metal to which the report described in paragraphs (b) and (c) of this section relates.

§ 280.16 Subsequent purchaser.

(a) If a purchaser of fasteners requests the seller to mark the container of fasteners with the lot number from which such fasteners were taken, either prior to the sale or at the time of sale, the seller shall conspicuously mark the container of fasteners with the lot number.

(b) The seller shall provide copies of any applicable laboratory testing report or certification of conformance upon request to the subsequent purchaser of fasteners taken from the lot to which such testing report or manufacturer's certificate of conformance relates.

Subpart B—Laboratory Accreditation

§ 280.100 Introduction.

The Fastener Quality Act sets out three alternatives by which a laboratory may become accredited for testing under the Act. This regulation sets out implementing procedures for each of those alternatives:

(a) Subpart C of this part contains procedures by which the National Institute of Standards and Technology's National Voluntary Laboratory Accreditation Program will accredit laboratories for the testing of fasteners under the Act;

(b) Subpart D of this part sets out procedures under which private entities may apply to NIST for approval to engage directly in the accreditation of laboratories for the testing of fasteners under the Act; and

(c) Subpart E of this part sets out conditions under which the accreditation of foreign laboratories by their governments or organizations recognized by the Director shall be deemed to satisfy the laboratory accreditation requirements for the testing of fasteners under the Act.

§ 280.101 Accredited laboratory list.

NIST shall prepare and maintain an Accredited Laboratory List of laboratories accredited under subparts C, D,

and E of this part. Only laboratory test reports covering tests performed by a laboratory listed in the Accredited Laboratory List at the time the report was issued, and which are within the scope of the laboratory's accreditation, shall be deemed to meet the requirements of the Act.

§ 280.102 Procedures for inclusion in the accredited laboratory list.

(a) NVLAP, and all entities approved by NIST under subpart D of this part or recognized by NIST under subpart E of this part shall promptly notify NIST of each accreditation action taken under subparts C, D, or E of this part, respectively. Accreditation actions include initial accreditation, denials of accreditation, renewals, suspensions, terminations, revocations and changes in scope. Notifications shall be filed with: Fastener Quality Act Program Manager, Office of Standards Services, National Institute of Standards and Technology, Gaithersburg, Maryland 20899.

(b) Each notification to NIST shall include the following information, in English: The name of the laboratory accreditation body which granted the accreditation; the name and address of the laboratory affected by the accreditation action; the nature of the accreditation action; a copy of the laboratory's accreditation certificate and a scope of accreditation which states the fastener test methods for which it has been accredited; the name and telephone number of the authorized representative(s) and approved signatory(s) of the fastener testing laboratory; information concerning the physical locations of all organizational units involved in accredited fastener testing, and the specific scope of fastener testing for each organizational unit for which accreditation has been granted.

(c) NIST shall revise as appropriate the Accredited Laboratory List when notified of accreditation actions and shall take appropriate steps to make information changes promptly available to the public.

§ 280.103 Removal from the accredited laboratory list.

(a) NIST may remove from the Accredited Laboratory List any fastener testing laboratory accredited under subpart C, D or E of this part if NIST deems such action to be in the public interest. Laboratory test reports describing tests performed by a laboratory after it has been removed from the Accredited Laboratory List under this section shall not be deemed to meet the requirements of the Act.

(b) A laboratory may appeal the removal or proposed removal from the Accredited Laboratory List to the Director by submitting a statement of reasons why the laboratory should remain on the list. NIST may, at its discretion, hold in abeyance a removal action pending a final decision by the Director. The Director shall inform the laboratory in writing of the decision within sixty days following receipt of the appeal.

Subpart C—NIST Fastener Laboratory Accreditation Procedures

§ 280.200 Introduction.

This subpart sets out the procedures and technical requirements of the NVLAP Fasteners Testing Program (''the Program'') for the accreditation of laboratories that test fasteners. Laboratories which are granted accreditation under this program for certain tests will be eligible to provide testing services and test reports required by the Fastener Quality Act for those tests. Accreditation may be granted to any laboratory (including: Commercial; manufacturers'; university; and laboratories located in foreign countries) that demonstrates competence to provide services according to the criteria specified in this subpart. It is up to the laboratory to select the areas and specific tests within each area for its proposed scope of accreditation. A laboratory may be accredited to test and/or measure fasteners in any one or more of the areas of chemical, dimensional, nondestructive, mechanical and physical, or metallography testing. Laboratories located outside of the U.S. must meet certain additional requirements including: Additional fees for travel outside the U.S. and provision of a language translator.

§ 280.201 Applicability of part 285, title 15, Code of Federal Regulations.

As permitted by section 6 of the Act, and for the purposes of that Act only, the provisions of part 285, title 15 of the Code of Federal Regulations are superseded by the procedures and requirements set forth in this Subpart. The provisions of part 285, title 15 of the Code of Federal Regulations remain in effect except as they pertain to laboratory accreditation actions required by the Act.

§ 280.202 Establishment of the Program.

(a) NVLAP shall develop the technical requirements for the Program based on expert advice.

(b) As a means of assuring effective and meaningful cooperation, input, and participation by those federal agencies that may have an interest in and may be affected by the Program, NVLAP may communicate and consult with appropriate officials within those agencies.

(c) When NVLAP has completed the development of the technical requirements of the Program and established a schedule of fees for accreditation, NVLAP shall publish a notice in the FEDERAL REGISTER announcing the establishment of the Program.

(d) The notice will:

(1) Identify the scope of the Program;

(2) Advise how to apply for accreditation.

(e) NVLAP shall establish fees in amounts that will enable the Program to be self-sufficient. NVLAP shall revise the fees when necessary to maintain self-sufficiency.

§ 280.203 Adding to or modifying the Program.

(a) The Program may be added to, modified, or realigned based on either a written request from any person wishing to add or delete specific standards, test methods, or types of test methods or a need identified by NVLAP.

(b) NVLAP may choose to make the additions or modifications available for accreditation when:

(1) The additional standards, test methods, or types of test methods requested are directly relevant to the Program;

(2) It is feasible and practical to accredit testing laboratories for the additional standards, test methods, or types of test methods; and

(3) It is likely that laboratories will seek accreditation for the additional standards, test methods, or types of test methods.

§ 280.204 NVLAP Program Handbook.

All specific laboratory accreditation requirements and NVLAP interpretations shall be documented in a program handbook which NVLAP shall develop and maintain. The handbook shall be made available to all participating laboratories. NVLAP may prepare a NVLAP Program Handbook for the Fastener Testing Program for use by applicant and accredited laboratories. The purpose of the handbook is to provide specific technical details for fastener testing as they apply to on-site assessment, proficiency testing, test equipment and facilities, and scope of accreditation.

§ 280.205 Applying for accreditation.

(a) A laboratory may request an application for accreditation in the Program in accordance with instructions provided in notices announcing the Program's formal establishment.

(b) Upon receipt of a laboratory's application, NVLAP shall:

(1) Acknowledge receipt of the application;

(2) Request further information, if necessary;

(3) Confirm payment of fees before proceeding with the accreditation process; and

(4) Specify the next step(s) in the accreditation process.

(c) All laboratory accreditation documents must be in English or the laboratory seeking accreditation must supply an English translation of all documents at the time it files its application.

(d) Accreditation of laboratories outside the United States may require payment of additional traveling expenses for on-site assessments and proficiency testing.

§ 280.206 Assessing and evaluating a laboratory.

(a) Information used to evaluate a laboratory's compliance with the conditions for accreditation set out in § 280.214, the criteria for accreditation set out in § 280.215, and the technical requirements established will include:

(1) Application and other material submitted by the laboratory (§ 280.214(b)).

(2) On-site assessment reports;

(3) Laboratory performance on proficiency tests;

(4) Laboratory responses to identified deficiencies; and

(5) Technical evaluation.

(b) NVLAP shall arrange the assessment and evaluation of applicant laboratories in such a way as to minimize potential conflicts of interest.

(c) NVLAP shall inform each applicant laboratory of any action(s) that the laboratory must take to qualify for accreditation.

§ 280.207 Granting and renewing accreditation.

(a) NVLAP will take action to grant initial accreditation, or renew, suspend, or propose to deny or revoke accreditation of an applicant laboratory, based on the degree to which the laboratory complies with the specific NVLAP requirements. Accreditation shall be granted for a one year period. Before initial accreditation and every 2 years thereafter, an on-site assessment of each laboratory shall be conducted to determine compliance with the NVLAP criteria.

(b) If accreditation is granted or renewed, NVLAP shall:

(1) Provide a Certificate of Accreditation and a Scope of Accreditation to the laboratory;

(2) Provide guidance on referencing the laboratory's accredited status, and the use of the NVLAP logo by the laboratory and its clients, as needed; and

(3) Remind the laboratory that accreditation does not relieve it from complying with applicable federal, state, and local laws and regulations.

(c) NVLAP shall notify an accredited laboratory at least 30 days before its accreditation expires advising of the action(s) the laboratory must take to renew its accreditation.

§ 280.208 Denying, suspending, and revoking accreditation.

(a) If NVLAP proposes to deny or revoke accreditation of a laboratory, NVLAP shall inform the laboratory of the reasons for the proposed denial or revocation and the procedure for appealing such a decision.

(b) The laboratory will have 30 days from the date of receipt of the proposed denial or revocation letter to appeal the decision to the Director of NIST. If the laboratory appeals the decision to the Director of NIST, the proposed denial or revocation will be stayed pending the outcome of the appeal. The proposed denial or revocation will become final through the issuance of a written decision to the laboratory in the event that the laboratory does not appeal the proposed denial or revocation within that 30-day period.

(c) If NVLAP finds that an accredited laboratory has violated the terms of its accreditation or the provisions of these procedures, NVLAP may, after consultation with the laboratory, suspend the laboratory's accreditation, or advise of NVLAP's intent to revoke accreditation. If accreditation is suspended, NVLAP shall notify the laboratory of that action stating the reasons for and conditions of the suspension and specifying the action(s) the laboratory must take to have its accreditation reinstated.

(d) A laboratory whose accreditation has been denied, revoked, terminated, or expired, or which has withdrawn its application before being accredited, may reapply and be accredited if the laboratory:

(1) Completes the assessment and evaluation process; and

(2) Meets the conditions and criteria for accreditation that are set out in sections 280.214 and 280.215.

(e) Conditions of suspension will include prohibiting the laboratory from using the NVLAP logo on its test reports during the suspension period. The determination of NVLAP whether to suspend or to propose revocation of a laboratory's accreditation will depend on the nature of the violation(s) of the terms of its accreditation.

§ 280.209 Voluntary termination of accreditation.

A laboratory may at any time terminate its participation and responsibilities as an accredited laboratory by advising NVLAP in writing of its desire to do so. NVLAP shall terminate the laboratory's accreditation and shall notify the laboratory stating that its accreditation has been terminated in response to its request.

§ 280.210 Change in status of laboratory.

Accreditation of a laboratory is based on specific conditions and criteria including the laboratory ownership, location, staffing, facilities, and configuration. Changes in any of these conditions or criteria could result in loss of accreditation. NVLAP must be informed if any of the conditions or criteria for accreditation are changed so that a determination can be made concerning the status of the accreditation.

§ 280.211 Authorized representative.

The laboratory shall designate an Authorized Representative to sign the NVLAP application form and commit the laboratory to fulfill the NVLAP requirements. Only the Authorized Representative can authorize a change in the scope or nature of the laboratory's application. This person will receive all correspondence and inquiries from NVLAP. The Authorized Representative may also be an Approved Signatory. The laboratory must provide to NVLAP the name and address of the Authorized Representative and must, within 30 days, notify NVLAP of a change of Authorized Representative.

§ 280.212 Approved signatory.

(a) The laboratory shall designate one or more staff members as Approved Signatories. Approved Signatories shall be persons with appropriate responsibility, authority and technical capability within the organization. The laboratory must maintain a list of Approved Signatories and make that list available for review during on-site assessments. The laboratory must provide to NVLAP the name(s) and address(es) of the Approved Signatory(s) and must, within 30 days, notify NVLAP of a change of Approved Signatory(s).

(b) The authorized signature of at least one Approved Signatory must appear on each test reports that is written in compliance with the Act and endorsed with the NVLAP logo. The approved signatory is responsible for the technical content of the report and is the person to be contacted by NVLAP, laboratory clients, or others in case of questions or problems with the report.

§ 280.213 Application of accreditation conditions and criteria.

To become accredited and maintain accreditation, a laboratory must meet the conditions for accreditation set out in § 280.214, the criteria set out in § 280.215, and the guidance provided in the Program Handbook.

§ 280.214 Conditions for accreditation.

(a) To become accredited and maintain accreditation, a laboratory shall agree in writing to:

(1) Be assessed and evaluated initially and on a periodic basis;

(2) Demonstrate, on request that it is able to perform the tests representative of those for which it is seeking accreditation;

(3) Pay all fees;

(4) Participate in proficiency testing as required.

(5) Be capable of performing the tests for which it is accredited according to the latest version of the test method within one year after its publication or within another time limit specified by NVLAP;

(6) Limit the representation of the scope of its accreditation to only those tests or services for which accreditation is granted;

(7) Resolve all deficiencies;

(8) Limit all its work or services for clients to those areas where competence and capacity are available;

(9) Inform its clients that the laboratory's accreditation or any of its test reports in no way constitutes or implies product certification, approval, or endorsement by NIST;

(10) Maintain records of all actions taken in response to testing complaints for 5 years, as required by § 280.7 of this part;

(11) Maintain an independent decisional relationship between itself and its clients, affiliates, or other organizations so that the laboratory's capacity to render test reports objectively and without bias is not adversely affected;

(12) Report to NVLAP within 30 days any major changes involving the location, ownership, management structure, authorized representative, approved signatories, or facilities of the laboratory; and

(13) Return to NVLAP the Certificate of Accreditation and the Scope of Accreditation for revision or other action should it:

(i) Be requested to do so by NVLAP;

(ii) Voluntarily terminate its accredited status; or

(iii) Become unable to conform to any of these conditions, the applicable criteria of this Subpart or §280.215, and related technical requirements.

(b) To become accredited and maintain accreditation, a laboratory shall supply, upon request, the following information:

(1) Legal name and full address;

(2) Ownership of the laboratory;

(3) Organization chart defining relationships that are relevant to performing testing covered in the accreditation request;

(4) General description of the laboratory, including its facilities and scope of operation;

(5) Name, address, and telephone and FAX number of the authorized representative of the laboratory;

(6) Names or titles and qualifications of laboratory staff nominated to serve as approved signatories of test reports that reference NVLAP accreditation;

(7) The laboratory quality manual; and

(8) Other information as NVLAP may require.

§280.215 Criteria for accreditation.

(a) *Scope.* (1) This section sets out the general requirements in accordance with which a laboratory has to demonstrate that it operates, if it is to be recognized as competent to carry out specific tests.

(2) Additional requirements and information which have to be disclosed for assessing competence or for determining compliance with other criteria may be specified by NVLAP, depending upon the specific character of the task of the laboratory.

(3) This section is for use by testing laboratories in the development and implementation of their quality systems. It will also be used by NVLAP in the determination of the competence of laboratories.

(b) *Organization and management.* (1) The laboratory shall be legally identifiable. It shall be organized and shall operate in such a way that its permanent, temporary and mobile facilities meet the requirements of this Subpart.

(2) The laboratory shall:

(i) Have managerial staff with the authority and resources needed to discharge their duties;

(ii) Have policies to ensure that its personnel are free from any commercial, financial and other pressures which might adversely affect the quality of their work;

(iii) Be organized in such a way that confidence in its independence of judgement and integrity is maintained at all times;

(iv) Specify and document the responsibility, authority and interrelation of all personnel who manage, perform or verify work affecting the quality of calibrations and tests;

(v) Provide supervision by persons familiar with the calibration or test methods and procedures, the objective of the calibration or test and the assessment of the results. The ratio of supervisory to non-supervisory personnel shall be such as to ensure adequate supervision;

(vi) Have a technical manager (however named) who has overall responsibility for the technical operations;

(vii) Have a quality manager (however named) who has responsibility for the quality system and its implementation. The quality manager shall have direct access to the highest level of management at which decisions are taken on laboratory policy or resources, and to the technical manager. In some laboratories, the quality manager may also be the technical manager or deputy technical manager;

(viii) Nominate deputies in case of absence of the technical or quality manager;

(ix) Have documented policy and procedures to ensure the protection of clients' confidential information and proprietary rights;

(x) Where appropriate, participate in interlaboratory comparisons and proficiency testing programs.

(c) *Quality system, audit and review.* (1) The laboratory shall establish and maintain a quality system appropriate to the type, range and volume of calibration and testing activities it undertakes. The elements of this system shall be documented. The quality documentation shall be available for use by the laboratory personnel. The laboratory shall define and document its policies and objectives for, and its commitment to, good laboratory practice and quality of calibration or testing services. The laboratory management shall ensure that these policies and objectives are documented in a quality manual and communicated to, understood, and implemented by all laboratory personnel concerned. The quality manual shall be maintained current under the responsibility of the quality manager.

(2) The quality manual, and related quality documentation, shall state the laboratory's policies and operational procedures established in order to meet the requirements of this subpart. The quality manual and related quality documentation shall also contain:

(i) A quality policy statement, including objectives and commitments, by top management;

(ii) The organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts;

(iii) The relations between management, technical operations, support services and the quality system;

(iv) Procedures for control and maintenance of documentation;

(v) Job descriptions of key staff and reference to the job descriptions of other staff;

(vi) Identification of the laboratory's approved signatories;

(vii) The laboratory's procedures for achieving traceability of measurements;

(viii) The laboratory's scope of calibrations and/or tests;

(ix) Arrangements for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;

(x) Reference to the calibration, verification and/or test procedures used;

(xi) Procedures for handling calibration and test items;

(xii) Reference to the major equipment and reference measurement standards used;

(xiii) Reference to procedures for calibration, verification and maintenance of equipment;

(xiv) Reference to verification practices including interlaboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes;

(xv) Procedures to be followed for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur;

(xvi) The laboratory management policies for departures from documented policies and procedures or from standard specifications;

(xvii) Procedures for dealing with complaints;

(xviii) Procedures for protecting confidentiality and proprietary rights;

(xix) Procedures for audit and review.

(xx) Policies and procedures directly related to compliance with this Subpart.

(3) The laboratory shall arrange for audits of its activities at appropriate intervals to verify that its operations continue to comply with the requirements of the quality system. Such audits shall be carried out by trained and qualified staff who are, wherever possible, independent of the activity to be audited. Where the audit findings cast doubt on the correctness or validity of the laboratory's calibration or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose work may have been affected.

(4) The quality system adopted to satisfy the requirements of this Section shall be reviewed at least once each year by the management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements.

(5) All audit and review findings and any corrective actions that arise from

them shall be documented. The person responsible for quality shall ensure that these actions are discharged within the agreed timescale.

(6) In addition to periodic audits the laboratory shall ensure the quality of results provided to clients by implementing checks. These checks shall be reviewed and shall include, as appropriate, but not be limited to:

(i) Internal quality control schemes using whenever possible statistical techniques;

(ii) Participation in proficiency testing or other interlaboratory comparisons;

(iii) Regular use of certified reference materials and/or in-house quality control using secondary reference materials;

(iv) Replicate testings using the same or different methods;

(v) Re-testing of retained items;

(vi) Correlation of results for different characteristics of an item.

(d) *Personnel.* (1) The testing laboratory shall have sufficient personnel, having the necessary education, training, technical knowledge and experience for their assigned functions.

(2) The testing laboratory shall ensure that the training of its personnel is kept up-to-date.

(3) Records on the relevant qualifications, training, skills and experience of the technical personnel shall be maintained by the laboratory.

(e) *Accommodation and environment.* (1) Laboratory accommodation, calibration and test areas, energy sources, lighting, heating and ventilation shall be such as to facilitate proper performance of calibrations or tests.

(2) The environment in which these activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises.

(3) The laboratory shall provide facilities for the effective monitoring, control and recording of environmental conditions as appropriate. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic interference, humidity, voltage, temperature, and sound and vibration levels, as appropriate to the calibrations or tests concerned.

(4) There shall be effective separation between neighboring areas when the activities therein are incompatible.

(5) Access to and use of all areas affecting the quality of these activities shall be defined and controlled.

(6) Adequate measures shall be taken to ensure good housekeeping in the laboratory.

(f) *Equipment and reference materials.* (1) The laboratory shall be furnished with all items of equipment (including reference materials) required for the correct performance of calibrations and tests. In those cases where the laboratory needs to use equipment outside its permanent control it shall ensure that the relevant requirements of this Section are met.

(2) All equipment shall be properly maintained. Maintenance procedures shall be documented. Any item of equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, shall be taken out of service, clearly identified and wherever possible stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests.

(3) Each item of equipment including reference materials shall, when appropriate, be labeled, marked or otherwise identified to indicate its calibration status.

(4) Records shall be maintained of each item of equipment and all reference materials significant to the calibrations or tests performed. The records shall include:

(i) The name of the item of equipment;

(ii) The manufacturer's name, type identification, and serial number or other unique identification;

(iii) Date received and date placed in service;

(iv) Current location, where appropriate;

(v) Condition when received (e.g. new, used, reconditioned);

(vi) Copy of the manufacturer's instructions, where available;

(vii) Dates and results of calibrations and/or verifications and date of next calibration and/or verification;

(viii) Details of maintenance carried out to date and planned for the future;

(ix) History of any damage, malfunction, modification or repair.

(g) *Measurement traceability and calibration.* (1) All measuring and testing equipment having an effect on the accuracy or validity of calibrations or tests shall be calibrated and/or verified before being put into service. The laboratory shall have an established program for the calibration and verification of its measuring and test equipment.

(2) The overall program of calibration and/or verification and validation of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the laboratory are traceable to national standards of measurement where available. Calibration certificates shall wherever applicable indicate the traceability to national standards of measurement and shall provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification.

(3) Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable program of interlaboratory comparisons or proficiency testing.

(4) Reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be demonstrated that their performance as reference standards has not been invalidated.

(5) Reference standards of measurement shall be calibrated by a body that can provide traceability to a national standard of measurement. There shall be a program of calibration and verification for reference standards.

(6) Where relevant, reference standards and measuring and testing equipment shall be subjected to in-service checks between calibrations and verifications.

(7) Reference materials shall, where possible, be traceable to national or international standards of measurement, or to national or international standard reference materials.

(h) *Calibration and test methods.* (1) The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of items and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

(2) The laboratory shall use appropriate methods and procedures for all calibrations and tests and related activities within its responsibility (including sampling, handling, transport and storage, preparation of items, estimation of uncertainty of measurement and analysis of calibration and/or test data). They shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations or tests concerned.

(3) Where methods are not specified, the laboratory shall, wherever possible, select methods that have been published in international or national standards, those published by reputable technical organizations or in relevant scientific texts or journals.

(4) Where it is necessary to employ methods that have not been established as standard, these shall be subject to agreement with the client, be fully documented and validated, and be available to the client and other recipients of the relevant reports.

(5) Where sampling is carried out as part of the test method, the laboratory shall use documented procedures and appropriate statistical techniques to select samples.

(6) Calculations and data transfers shall be subject to appropriate checks.

(7) Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of calibration or test data, the laboratory shall ensure that:

(i) The requirements of this subpart are complied with;

(ii) Computer software is documented and adequate for use;

(iii) Procedures are established and implemented for protecting the integrity of data; such procedures shall include, but not be limited to, integrity of data entry or capture, data storage, data transmission and data processing;

(iv) Computer and automated equipment is maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data;

(v) It establishes and implements appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

(8) Documented procedures shall exist for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory.

(i) *Handling of calibration and test items.* (1) The laboratory shall have a documented system for uniquely identifying the items to be calibrated or tested, to ensure that there can be no confusion regarding the identity of such items at any time.

(2) Upon receipt, the condition of the calibration or test item, including any abnormalities or departures from standard conditions as prescribed in the relevant calibration or test method, shall be recorded. Where there is any doubt as to the item's suitability for calibration or test, where the item does not conform to the description provided, or where the calibration or test required is not fully specified, the laboratory shall consult the client for further instruction before proceeding. The laboratory shall establish whether the item has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory.

(3) The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or damage to the calibration or test item, during storage, handling, preparation, and calibration or test; any relevant instructions provided with the item shall be followed. Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded where necessary. Where a calibration or test item or portion of an item is to be held secure (for example, for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned.

(4) The laboratory shall have documented procedures for the receipt, retention or safe disposal of calibration or test items, including all provisions necessary to protect the integrity of the laboratory.

(j) *Records.* (1) The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable regulations. It shall retain on record all original observations, calculations and derived data, calibration records and a copy of the calibration certificate, test certificate or test report for an appropriate period as required in §280.7. The records for each calibration and test shall contain sufficient information to permit their repetition. The records shall include the identity of personnel involved in sampling, preparation, calibration or testing.

(2) All records (including those listed in §280.215(f)(4) pertaining to calibration and test equipment), certificates and reports shall be safely stored, held secure and in confidence to the client.

(k) *Certificates and reports.* (1) The results of each calibration, test, or series of calibrations or tests carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, in accordance with any instructions in the calibration or test methods. The results should normally be reported in a calibration certificate, test report or test certificate and should include all the information necessary for the interpretation of the calibration or test results and all information required by the method used.

(2) Where the certificate or report contains results of calibrations or tests performed by sub-contractors, these results shall be clearly identified.

(3) Particular care and attention shall be paid to the arrangement of the certificate or report, especially with

regard to presentation of the calibration or test data and ease of assimilation by the reader. The format shall be carefully and specifically designed for each type of calibration or test carried out, but the headings shall be standardized as far as possible.

(4) Material amendments to a calibration certificate, test report or test certificate after issue shall be made only in the form of a further document, or data transfer including the statement ''Supplement to Calibration Certificate for Test Report or Test Certificate, serial number * * * or as otherwise identified'', or equivalent form of wording. Such amendments shall meet all the relevant requirements of §280.215(j).

(5) The laboratory shall notify clients promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any calibration certificate, test report or test certificate or amendment to a report or certificate.

(6) The laboratory shall ensure that, where clients require transmission of calibration or test results by telephone, telex, facsimile or other electronic or electromagnetic means, staff will follow documented procedures that ensure that the requirements of this Subpart are met and that confidentiality is preserved.

(l) *Subcontracting of calibration or testing.* (1) Where a laboratory sub-contracts any part of the calibration or testing, this work shall be placed with a laboratory accredited under either subparts C, D or E of this part for the specific tests being subcontracted. The laboratory shall comply with §280.9, and shall advise the client in writing of its intention to subcontract any portion of the testing to another party.

(2) The laboratory shall record and retain details of its investigation of the accredited status and testing competence of subcontractors and maintain a register of all subcontracting.

(m) *Outside support services and supplies.* (1) Where the laboratory procures outside services and supplies, other than those referred to this Subpart, in support of calibrations or tests, the laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's calibrations or tests.

(2) Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall have procedures to ensure that purchased equipment, materials and services comply with specified requirements. The laboratory should, wherever possible, ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the calibrations or tests concerned.

(3) The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for calibrations or tests.

(n) *Complaints.* (1) The laboratory shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities. A record shall be maintained of all complaints and of the actions taken by the laboratory.

(2) Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of this section or otherwise concerning the quality of the laboratory's calibrations or tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with this section.

Subpart D—NIST Approval of Private Accreditation Programs

§280.300 Introduction.

In accordance with section 6(a)(1)(B) of the Act (15 U.S.C. 5405 (a)(1)(B)), this subpart sets forth the procedures and conditions under which private entities may apply for approval by NIST to engage directly in the accreditation of laboratories for the testing of fasteners under the Act.

§280.301 Application.

(a) Application must be made to NIST for approval to accredit laboratories for fastener testing under the Act. Upon request, NIST will provide

application forms and instructions. The applicant shall complete the application in English and may provide whatever additional enclosures, attachments or exhibits the applicant deems appropriate.

(b) Application packages may be obtained from: Manager, FQA Accreditation Body Evaluation Program, NIST, Bldg. 820, Room 282, Gaithersburg, Maryland, 20899. Requests may be made by mail or by FAX to: (301) 963–2871.

(c) The applicant shall reimburse NIST for all costs incurred in the evaluation of its accreditation program and subsequent costs incurred in ensuring the continued compliance of its program. Reimbursement shall be in accordance with the fee schedule established by NIST for this purpose.

(d) An application may be revised by an applicant at any time prior to the final decision by NIST. An application may be withdrawn by an applicant, without prejudice, at any time prior to the final decision by the Director.

§ 280.302 Review and decision process.

(a) Applications submitted by private laboratory accreditation bodies will be accepted by NIST and their receipt acknowledged in writing. The applications will be reviewed by NIST against the criteria specified in this subpart and in subpart F of this part. NIST may request additional information as needed from the applicant.

(b) NIST shall conduct on-site assessments of the facilities of the applicant including all of the applicant's organizational units and locations covered by the application.

(c) If the applicant's program is deemed by NIST to have met the requirements for approval, the applicant shall be notified by NIST in writing. The approval notice shall include the dates when the approval begins and the scope of the approval. The approval period shall be for as long as the laboratory accreditation body continues to satisfy the requirements of § 280.303. As part of maintaining its approved status, each laboratory accreditation body shall agree to be reassessed by NIST every two years following its initial notice of approval. NIST will maintain and make available to the public a list of approved fastener accreditation programs.

(d) If the applicant's program does not meet the requirements for approval, the applicant shall be notified in writing, listing the specific requirements from this subpart and subpart F of this part which the applicant's program has not met. After receipt of such a notification, and within the response period provided by NIST, the applicant may:

(1) Submit additional information for further review. Reviewing the new submission may involve additional on-site visits by NIST personnel. Additional fees may be required. Or,

(2) Submit a request that the original application be reconsidered, including a statement of reasons why the application should have been approved.

§ 280.303 Criteria for approval.

An applicant for NIST approval must demonstrate the ability to operate an accreditation program consistent with the requirements of this subpart and subparts A, B and F of this part.

§ 280.304 Maintaining approved status.

(a) Approved accreditation bodies shall continue to satisfy all the requirements of approval during the approval period.

(b) Upon request by NIST, approved accreditation bodies shall make available to NIST and BXA all records and materials pertaining to the program.

(c) NIST may elect to have its representative participate as an observer during on-site visits to testing laboratories seeking accreditation by an approved accreditation body.

(d) Neither the accreditation body, nor any laboratory it accredits under the Act and these regulations shall take any action which states or implies the approval, or endorsement by NIST or any other agency of the U.S. government of the results of tests carried out by such laboratories. In addition, neither the accreditation body, nor any laboratory it accredits under the Act and these regulations shall take any action which states or implies that the accreditation body or its accredited laboratories are recognized by NIST in any testing or other area(s) beyond those for which NIST has approved the

accreditation body under this regulation. Approved accreditation bodies shall not engage in misrepresentation of the scope or conditions of its approval by NIST.

§ 280.305 Voluntary termination of approval.

At any time, an accreditation body may voluntarily terminate its program's approval by giving written notice to NIST and to all laboratories accredited by that body under its fastener laboratory accreditation program. The written notice shall state the date on which the termination will take effect.

§ 280.306 Involuntary termination of approval by NIST.

(a) NIST may terminate or suspend its approval of an accreditation body if such an action is deemed to be in the public interest.

(b) Before terminating the approval of an accreditation body, NIST will notify the accreditation body in writing, giving it the opportunity to rebut or correct the stated reasons for the proposed termination. If the problems are not corrected or reconciled within 30 days, or such longer time as NIST in its sole discretion may grant, the termination shall become effective.

(c) An accreditation body may appeal a termination to the Director by submitting a statement of reasons why the approval should not be terminated. NIST may, at its discretion, hold in abeyance the termination action pending a final decision by the Director. Within sixty days following receipt of the appeal, the Director shall inform the accreditation body in writing of his or her decision.

(d) Fastener testing laboratories which have been listed by NIST in accordance with subpart B of this part, based on their accreditation by an accreditation body whose approval has terminated, shall be removed from the list, unless an exception is granted by NIST.

Subpart E—Recognition of Foreign Laboratories

§ 280.400 Introduction.

In accordance with section 6(a)(1)(C) of the Act, this subpart sets forth the conditions under which the accreditation of foreign laboratories by their governments, by organizations acting on behalf of their governments, or by organizations recognized by the Director shall be deemed to meet the requirements of the Act.

§ 280.401 Recognition of foreign laboratories.

Foreign entities wishing to be recognized to accredit fastener testing laboratories must submit an application for evaluation to NIST. NIST recognition is limited to bodies that accredit laboratories performing tests on materials or fasteners covered by the Act. To be recognized by NIST, accredited foreign laboratories must meet conditions set out in subpart C of this part, and applicable laboratory accreditation bodies must meet conditions set out in subparts D and F of this part.

Subpart F—Requirements for Fastener Laboratory Accreditation Bodies

§ 280.500 Introduction.

This subpart sets out organizational, operational and other requirements that must be met by all accreditation bodies approved or recognized (hereafter ''approved/recognized'') by NIST under subpart D or E of this part. This subpart also sets out the requirements against which an approved/recognized accreditation body assesses the technical competence of an applicant testing laboratory. These requirements include conditions with respect to subpart C of this part.

§ 280.501 Accreditation bodies.

(a) *General provisions.* (1) The procedures under which an approved/recognized accreditation body operates shall

be administered in a non-discriminatory manner. Access to an accreditation system operated by an approved/recognized accreditation body shall not be conditional upon the size of the laboratory or membership in any association or group, nor shall there be undue financial conditions to restrict participation.

(2) The competence of an applicant laboratory shall be assessed by an approved/recognized accreditation body against requirements consistent with the conditions set out in subpart C of this part.

(3) The requirements of § 280.501(a)(2) may have to be interpreted for a specific test or type of test by an approved/recognized accreditation body. These interpretations shall be formulated by relevant and impartial committees or persons possessing the necessary technical competence. They shall be published by the accreditation body.

(4) An approved/recognized accreditation body shall require accredited laboratories to maintain impartiality and integrity.

(5) An approved/recognized accreditation body shall confine its requirements, assessment and decision on accreditation to those matters specifically related to the scope of the accreditation being considered.

(b) *Organization of an approved/recognized accreditation body*. (1) An approved/recognized accreditation body shall:

(i) Be a legally identifiable, public or private entity;

(ii) Have rights and responsibilities relevant to its accreditation activities;

(iii) Have adequate arrangements to cover liabilities arising from its operations and/or activities;

(iv) Have the financial stability and resources required for the operation of an accreditation system;

(v) Have and make available on request a description of the means by which it receives its financial support;

(vi) Employ a sufficient number of personnel having the necessary education, training, technical knowledge and experience for handling the type, range and volume of work performed, under a senior executive who is responsible to the organization, body or board to which it reports;

(vii) Have a quality system including an organizational structure, that enables it to give confidence in its ability to operate a laboratory accreditation system satisfactorily;

(viii) Have documented policies and procedures for the operation of the quality system that include:

(A) Policies and decision-making procedures that distinguish between laboratory accreditation and any other activities in which the body is engaged;

(B) Policies and procedures for the resolution of complaints and appeals received from laboratories about the handling of accreditation matters, or from users of services about accredited laboratories or any other matters;

(ix) Together with its senior executive, and staff, be free from any commercial, financial and other pressures which might influence the results of the accreditation process;

(x) Have formal rules and structures for the appointment and operation of committees involved in the accreditation process; such committees shall be free from any commercial, financial and other pressures that might influence decisions or shall have a structure where members are chosen to provide impartiality through a balance of interest where no single interest predominates;

(xi) Establish one or more technical committees, each responsible, within its scope, for advising the accreditation body on the technical matters relating to the operation of its accreditation system;

(xii) Not offer consultancies or other services which may compromise the objectivity of its accreditation process and decisions;

(xiii) Have arrangements that are consistent with applicable laws, to safeguard, at all levels of its organization (including committees), confidentiality of the information obtained relating to applications, assessment and accreditation of laboratories;

(2) An approved/recognized accreditation body shall have arrangements for either controlling the ownership, use and display of the accreditation documents or controlling the manner in

which an accredited laboratory may refer to its accredited status, or both.

(c) *Quality system.* (1) An approved/recognized accreditation body shall operate a quality system appropriate to the type, range and volume of work performed. This system shall be documented and the documentation shall be available for use by the accreditation body staff. The accreditation body shall designate a person having direct access to its highest executive level, to take responsibility for the quality system and the maintenance of the quality documentation.

(2) The quality system shall be documented in a quality manual and associated quality procedures, and the quality manual shall contain or refer to at least the following;

(i) A quality policy statement;

(ii) The organizational structure of the accreditation body;

(iii) The operational and functional duties and services pertaining to quality, so that each person concerned will know the extent and the limits of their responsibility;

(iv) Administrative procedures including document control;

(v) Policies and procedures to implement the accreditation process;

(vi) Arrangements for feedback and corrective actions whenever discrepancies are detected;

(vii) The policy and procedures for dealing with appeals, complaints and disputes;

(viii) The policy and procedures for conducting internal audits;

(ix) The policy and the procedures for conducting quality system reviews;

(x) The policy and the procedures for the recruitment and training of assessors and monitoring their performance.

(3) An approved/recognized accreditation body shall audit its activities to verify that they comply with the requirements of the quality system. The quality system shall also be reviewed to ensure its continued effectiveness. Audits and reviews shall be carried out systematically and periodically and recorded together with details of any corrective actions taken.

(4) An approved/recognized accreditation body shall maintain records to demonstrate that accreditation procedures have been effectively fulfilled, particularly with respect to application forms, assessment reports, and reports relating to granting, maintaining, extending, suspending or withdrawing accreditation. These accreditation documents shall form part of the record.

(5) An approved/recognized accreditation body shall have a policy and procedures for retaining records. The records shall be retained for a period of at least 5 years, and shall be available to NIST personnel and other persons considered by the accreditation body to have a right of access to these records.

(d) *Granting, maintaining, extending, suspending, and withdrawing accreditation.* (1) An approved/recognized accreditation body shall specify the conditions for granting, maintaining and extending accreditation and the conditions under which accreditation may be suspended or withdrawn, partially or in total for all or part of the laboratory's scope of accreditation.

(2) An approved/recognized accreditation body shall have arrangements to grant, maintain, suspend or withdraw accreditation, increase or reduce the scope of accreditation or require reassessment, in the event of changes affecting the laboratory's activity and operation, such as changes in personnel or equipment, or if analysis of a complaint or any other information indicates that the laboratory no longer complies with the requirements of the accreditation body.

(3) An approved/recognized accreditation body shall have arrangements relating to the transfer of accreditation when the legal status (e.g. ownership) of the accredited laboratory changes.

(e) *Documentation.* An approved/recognized accreditation body shall provide (through publications, electronic media or other means), update at adequate intervals, and make available on request:

(1) Information about the authority under which accreditation systems operated by the accreditation body were established and specifying whether they are mandatory or voluntary;

(2) A document containing its requirements for accreditation in accordance with this document;

(3) A document stating the arrangements for granting, maintaining, extending, suspending and withdrawing accreditation;

(4) Information about the assessment and accreditation process;

(5) General information on the fees charged to applicant and accredited laboratories;

(6) A description of the rights and duties of accredited laboratories as specified in § 280.504 of this part, including requirements, restrictions or limitations on the use of the accrediting body's logo and on the ways of referring to the accreditation granted.

§ 280.502 Laboratory assessors.

(a) *Requirements for assessors.* The assessor or assessment team appointed to assess a laboratory shall:

(1) Be familiar with the relevant legal regulations, accreditation procedures and accreditation requirements;

(2) Have a thorough knowledge of the relevant assessment method and assessment documents;

(3) Have appropriate technical knowledge of the specific tests or types of tests for which accreditation is sought and, where relevant, with the associated sampling procedures;

(4) Be able to communicate effectively, both in writing and orally;

(5) Be free of any commercial, financial or other pressures or conflicts of interest that might cause assessor(s) to act in other than an impartial or nondiscriminatory manner;

(6) Not have offered consultancies to laboratories which might compromise their impartiality in the accreditation process and decisions.

(b) *Qualification procedures for assessors.* An approved/recognized accreditation body shall have an adequate procedure for:

(1) Qualifying assessors, comprising an assessment of their competence and training, and attendance at one or more actual assessments with a qualified assessor, and

(2) Monitoring the performance of assessors.

(c) *Contracting of assessors.* An approved/recognized accreditation body shall require the assessors to sign a contract or other document by which they commit themselves to comply with the rules defined by the accreditation body, including those relating to confidentiality and those relating to independence from commercial and other interests, and any prior association with laboratories to be assessed.

(d) *Assessor records.* An approved/recognized accreditation body shall possess and maintain up-to-date records on assessors consisting of:

(1) Name and address;

(2) Organization affiliation and position held;

(3) Educational qualification and professional status;

(4) Work experience;

(5) Training in quality assurance, assessment and calibration and testing;

(6) Experience in laboratory assessment, together with field of competence;

(7) Date of most recent updating of record.

(e) *Procedures for assessors.* Assessors shall be provided with an up-to-date set of procedures giving assessment instructions and all relevant information on accreditation arrangements.

§ 280.503 Accreditation process.

(a) *Application for accreditation.* (1) A detailed description of the assessment and accreditation procedure, the documents containing the requirements for accreditation and documents describing the rights and duties of accredited laboratories (including fees to be paid by applicant and accredited laboratories) shall be maintained up-to-date and given to applicant laboratories.

(2) Additional relevant information shall be provided to applicant laboratories on request.

(3) A duly authorized representative of the applicant laboratory shall be required to sign an official application form, in which or attached to which

(i) The scope of the desired accreditation is clearly defined;

(ii) The applicant's representative agrees to fulfill the accreditation procedure, especially to receive the assessment team, to pay the fees charged to the applicant laboratory whatever the result of the assessment may be, and to accept the charges of subsequent maintenance of the accreditation of the laboratory;

(iii) the applicant agrees to comply with the requirements for accreditation and to supply any information needed for the evaluation of the laboratory.

(4)(i) The following minimum information shall be provided by the applicant laboratory prior to the on-site assessment:

(A) The general features of the applicant laboratory (corporate entity: Name, address, legal status, human and technical resources);

(B) General information concerning the laboratory covered by the application, such as primary function, relationship in a larger corporate entity and, If applicable, physical location of laboratories involved;

(C) A definition of the materials or products tested, the methods used and the tests performed;

(D) A copy of the laboratory's quality manual and, where required, the associated documentation.

(ii) The information gathered shall be used for the preparation of on-site assessment and shall be treated with appropriate confidentiality.

(b) *Assessment.* (1) An approved/recognized accreditation body shall appoint qualified assessor(s) to evaluate all material collected from the applicant and to conduct the assessment on its behalf at the laboratory and any other sites where activities to be covered by the accreditation are performed.

(2) To ensure that a comprehensive and correct assessment is carried out, each assessor shall be provided with the appropriate working documents.

(3) The date of assessment shall be mutually agreed with the applicant laboratory. The latter shall be informed of the name(s) of the qualified assessor(s) nominated to carry out the assessment, with sufficient notice so that the laboratory is given an opportunity to appeal against the appointment of any particular assessor.

(4) The assessor(s) shall be formally appointed. A lead assessor shall be appointed, if relevant. The mandate given to the assessor(s) shall be clearly defined and made known to the applicant laboratory.

(c) *Sub-contracting of assessment.* (1) If an approved/recognized accreditation body decides to delegate fully or partially the assessment of a laboratory to another body, then the accreditation body shall take full responsibility for such an assessment made on its behalf.

(2) An approved/recognized accreditation body shall ensure that the party to which assessment has been delegated is approved/recognized by NIST.

(d) *Assessment report.* (1) An approved/recognized accreditation body may adopt reporting procedures that suit its needs but as a minimum these procedures shall ensure that:

(i) A meeting takes place between the assessor or assessment team and the laboratory management prior to leaving the laboratory at which the assessment team provides a written or oral report on the compliance of the applicant laboratory with the accreditation requirements;

(ii) The assessor or assessment team provides the accreditation body with a detailed assessment report containing all relevant information concerning the ability of the applicant laboratory to comply with all of the accreditation requirements, including any which may come about from the results of proficiency testing;

(iii) A report on the outcome of the assessment is promptly brought to the applicant laboratory's notice by the accreditation body, identifying any non-compliances that have to be discharged in order to comply with all of the accreditation requirements. The laboratory shall be invited to present its comments on this report and to describe the specific actions taken, or planned to be taken within a defined time, to remedy any non-compliances with the accreditation requirements identified during the assessment.

(2) The final report authorized by an approved/recognized accreditation body and submitted to the laboratory, if it is different, shall include as a minimum:

(i) Date(s) of assessment(s);

(ii) The names of the person(s) responsible for the report;

(iii) The names and addresses of all the laboratory sites assessed;

(iv) The assessed scope of accreditation or reference thereto;

(v) comments of the assessor(s) or assessment team on the compliance of the applicant laboratory with the accreditation requirements.

(3) The reports shall take into consideration:

(i) The technical qualification, experience and authority of the staff encountered, especially the persons responsible for the technical validity of test reports or test certificates;

(ii) The adequacy of the internal organization and procedures adopted by the applicant laboratory to give confidence in the quality of its services, the physical facilities, i.e., the environment and the calibration/test equipment of the laboratory including maintenance and calibration having regard to the volume of work undertaken;

(iii) Proficiency testing or other interlaboratory comparison performed by the applicant laboratory, the results of this proficiency testing, and the use of these results by the laboratory;

(iv) The actions taken to correct any non-compliances identified at previous assessments.

(e) *Decision on accreditation.* (1) The decision whether or not to accredit a laboratory shall be taken by an approved/recognized accreditation body on the basis of the information gathered during the accreditation process.

(2) An approved/recognized accreditation body shall not delegate its responsibility for granting, maintaining, extending, suspending or withdrawing accreditation.

(f) *Granting accreditation.* (1) An approved/recognized accreditation body shall transmit to each accredited laboratory formal accreditation documents such as a letter or a certificate signed by an officer who has been assigned such responsibility. These formal accreditation documents shall permit identification of—

(i) The name and address of the laboratory that has been accredited;

(ii) The scope of the accreditation including:

(A) The tests or types of test for which accreditation has been granted;

(B) For tests, the materials or products tested, the methods used and the tests performed;

(C) For specific tests for which accreditation has been granted the methods used defined by written standards or reference documents that have been accepted by the accreditation body.

(iii) Where appropriate, the persons recognized by the accreditation body as being responsible for the test certificates or the test reports;

(iv) The term of accreditation which shall be valid for a period not to exceed three years;

(v) The accredited laboratory by a unique number.

(2) An approved/recognized accreditation body shall furnish notification to NIST required by Subpart B of this part.

(g) *Surveillance and reassessment of accredited laboratories.* (1) An approved/recognized accreditation body shall have an established documented program consistent with the accreditation granted for carrying out periodic surveillance and reassessment at sufficiently close intervals to ensure that its accredited laboratories continue to comply with the accreditation requirements.

(2) Surveillance and reassessment procedures shall be consistent with those concerning the assessment of laboratories as described in this Subpart.

(h) *Proficiency testing.* (1) The approved/recognized accreditation body shall require each fastener testing laboratory it accredits, and each laboratory which has applied to it for accreditation to participate in proficiency testing comparable to that conducted under Subpart C of this part by NVLAP.

(2) Although an accreditation shall not be granted or maintained only on the basis of the results of proficiency testing, accreditation shall not be granted or maintained if required proficiency testing participation is unsatisfactory.

(i) *Certificates or reports issued by accredited laboratories.* (1) An approved/recognized accreditation body shall normally allow an accredited laboratory to refer to its accreditation in test reports and test certificates that contain only the results of tests or types of test for which accreditation is held.

(2) An approved/recognized accreditation body shall have a policy that defines the circumstances in which accredited laboratories are permitted to

include in test reports or test certificates, the results of tests for which accreditation is not held and the results of sub-contracted tests.

§ 280.504 Relationship between approved/recognized accreditation body and laboratory.

(a) An approved/recognized accreditation body shall have arrangements to ensure that the laboratory and its representatives afford such accommodation and co-operation as is necessary, to enable the accreditation body to verify compliance with the requirements for accreditation. These arrangements shall include provision for examination of documentation and access to all testing areas, records and personnel for the purposes of assessment, surveillance, reassessment and resolution of complaints.

(b) An approved/recognized accreditation body shall require that an accredited laboratory—

(1) At all times complies with the relevant provisions of these regulations;

(2) Claims that it is accredited only in respect of services for which it has been granted accreditation and which are carried out in accordance with these conditions;

(3) Pays such fees as shall be determined by the accreditation body;

(4) Does not use its accreditation in such a manner as to bring the accreditation body into disrepute and does not make any statement relevant to its accreditation which the accreditation body may consider misleading or unauthorized;

(5) Upon suspension or withdrawal of its accreditation (however determined) forthwith discontinues its use of all advertising matter that contains any reference thereto and return any certificates of accreditation to the accreditation body;

(6) Does not use its accreditation to state or imply any product approval by the accreditation body or any agency of the United States Government;

(7) Endeavors to ensure that no certificate or report nor any part thereof is used in a misleading manner;

(8) In making reference to its accreditation status in communication media such as advertising, brochures or other documents, complies with the requirements of the accreditation body.

(c) *Notification of change.* (1) An approved/recognized accreditation body shall have arrangements to ensure that an accredited laboratory informs it without delay of changes in any aspect of the laboratory's status or operation that affects the laboratory's:

(i) Legal, commercial or organizational status;

(ii) Organization and management, e.g., key managerial staff;

(iii) Policies or procedures, where appropriate;

(iv) Premises;

(v) Personnel, equipment, facilities, working environment or other resources, where significant;

(vi) Authorized signatories;

(vii) Or other such matters that may affect the laboratory's capability, or scope of accredited activities, or compliance with the requirements in this document or any other relevant criteria of competence specified by the accreditation body.

(2) Upon receipt of due notice of any intended changes relating to the requirements of this document, the relevant criteria of competence and any other requirements prescribed by the accreditation body, the accreditation body shall ensure that the laboratory carries out the necessary adjustments to its procedures within such time, as in the opinion of the body is reasonable. The laboratory shall notify the body when such adjustments have been made.

(d) *Directory of accredited laboratories.* An approved/recognized accreditation body shall produce periodically but at least annually a directory of accredited laboratories describing the accreditation granted.

Subpart G—Enforcement

§ 280.600 Scope.

Section 280.601 of this part lists definitions used in this part. Section 280.602 of this part specifies that failure to take any action required by or taking any action prohibited by this part constitutes a violation of this part. Section 280.603 describes the penalties that may be imposed for violations of this part. Sections 280.605 through

280.623 establish the procedures for imposing administrative penalties for violations of this part.

§ 280.601 Definitions used in this subpart.

The definitions in this § 280.601 apply to this part.

Administrative law judge (ALJ). The person authorized to conduct hearings in administrative enforcement proceedings brought under the Act.

Assistant Secretary. The Assistant Secretary for Export Enforcement, Bureau of Export Administration.

Department. The United States Department of Commerce, specifically, the Bureau of Export Administration, NIST and the Patent and Trademark Office.

Final decision. A decision or order assessing a civil penalty or otherwise disposing of or dismissing a case, which is not subject to further review under this part, but which is subject to collection proceedings or judicial review in an appropriate Federal district court as authorized by law.

Initial decision. A decision of the administrative law judge which is subject to review by the Under Secretary for Export Administration, but which becomes the final decision of the Department in the absence of such an appeal.

Party. The Department and any person named as a respondent under this part.

Respondent. Any person named as the subject of a charging letter, proposed charging letter, or other order proposed or issued under this part.

Under Secretary. The Under Secretary for Export Administration, United States Department of Commerce.

§ 280.602 Violations.

(a) *Engaging in prohibited conduct.* No person may engage in any conduct prohibited by or contrary to, or refrain from engaging in any action required by the Act, this part, or any order issued thereunder.

(b) *Causing, aiding, or abetting a violation.* No person may cause or aid, abet, counsel, command, induce, procure, or permit the doing of any act prohibited, or the omission of any act required, by the Act, this part, or any order issued thereunder.

(c) *Solicitation and attempt.* No person may solicit or attempt a violation of the Act, this part, or any order issued thereunder.

(d) *Conspiracy.* No person may conspire or act in concert with one or more persons in any manner or for any purpose to bring about or to do any act that constitutes a violation of the Act, this part, or any order issued thereunder.

(e) *Misrepresentation and concealment of facts.* No person may make any false or misleading representation, statement, or certification, or falsify or conceal any material fact, either directly to NIST, or the Bureau of Export Administration, the Patent and Trademark Office, or any official of any other United States agency, or indirectly through any other person:

(1) In the course of an investigation or other action subject to the Act and this part; or

(2) In connection with the preparation, submission, issuance, use, maintenance of a laboratory test report, certificate of conformance as described in §§ 280.5 and 280.6 of this part; or

(3) In connection with any application for laboratory accreditation as described in § 280.205 of this part; or

(4) In connection with an application to be an accreditation body as described in § 280.301 of this part.

(f) *Falsification of test report.* No person shall falsify or make any false or misleading statement on or in connection with a laboratory test report required by section 5(c) of the Act or § 280.6 of this part.

(g) *Falsification of certificate of conformance.* No person shall falsify or make any false or misleading statement on or in connection with a certificate of conformance required by § 280.5 of this part.

(h) *Falsification of documents relating to laboratory accreditation or accreditation bodies.* No person shall falsify or make any false or misleading statement on or in connection with any document relating to laboratory accreditation or approval or recognition of accreditation bodies as required by sections 6(a) or 6(b) of the Act or this part.

(i) *Use of another person's recorded insignia.* No person may apply an insignia to a fastener if the Commissioner has

issued a certificate of recordal (as described in § 280.712 of this part) for that insignia to another person without written permission from the person to whom the certificate was issued.

(j) *False claim of laboratory accreditation or accreditation body*. No person shall falsely claim to be an accredited laboratory or approved or recognized accreditation body as described in section 6 of the Act or subparts B, C, D, and E of this part.

§ 280.603 Penalties, remedies, and sanctions.

(a) *Civil remedies.* The Attorney General may bring an action in an appropriate United States district court for declaratory and injunctive relief against any person who violates the Act or any regulation issued thereunder. Such action may not be brought more than 10 years after the cause of action accrues.

(b) *Civil penalties.* Any person who is determined, after notice and opportunity for a hearing, to have violated the Act or any regulation issued thereunder shall be liable to the United States for a civil penalty of not more than $25,000 for each violation.

(c) *Criminal penalties.* (1) Whoever knowingly certifies, marks, offers for sale, or sells a fastener in violation of the Act or a regulation issued thereunder shall be fined under title 18, United States Code, or imprisoned not more than 5 years, or both.

(2) Whoever intentionally fails to maintain records relating to a fastener in violation of the Act or a regulation issued thereunder shall be fined under title 18, United States Code, or imprisoned not more than five years or both.

(3) Whoever negligently fails to maintain records relating to a fastener in violation of the Act or a regulation issued thereunder shall be fined under title 18, United States Code, or imprisoned not more than two years or both.

§ 280.604 Administrative enforcement proceedings.

Sections 280.605 through 280.623 set forth the procedures for imposing administrative penalties for violations of the Act and Fastener Quality Regulations (FQR).

§ 280.605 Institution of administrative enforcement proceedings.

(a) *Charging letters.* The Director of the Office of Export Enforcement (OEE) may begin administrative enforcement proceedings under this part by issuing a charging letter. The charging letter shall constitute the formal complaint and will state that there is reason to believe that a violation of this part has occurred. It will set forth the essential facts about each alleged violation, refer to the specific regulatory or other provisions involved, and give notice of the sanctions available under the Act and this part. The charging letter will inform the respondent that failure to answer the charges as provided in § 280.608 of this part will be treated as a default under § 280.609 of this part, that the respondent is entitled to a hearing if a written demand for one is requested with the answer, and that the respondent may be represented by counsel, or by other authorized representative. A copy of the charging letter shall be filed with the administrative law judge, which filing shall toll the running of the applicable statute of limitations. Charging letters may be amended or supplemented at any time before an answer is filed, or, with permission of the administrative law judge, afterwards. The Department may unilaterally withdraw charging letters at any time, by notifying the respondent and the administrative law judge.

(b) *Notice of issuance of charging letter instituting administrative enforcement proceeding.* A respondent shall be notified of the issuance of a charging letter, or any amendment or supplement thereto:

(1) By mailing a copy by registered or certified mail addressed to the respondent at the respondent's last known address;

(2) By leaving a copy with the respondent or with an officer, a managing or general agent, or any other agent authorized by appointment or by law to receive service of process for the respondent; or

(3) By leaving a copy with a person of suitable age and discretion who resides at the respondent's last known dwelling.

(4) Delivery of a copy of the charging letter, if made in the manner described in paragraph (b)(2) or (3) of this section, shall be evidenced by a certificate of service signed by the person making such service, stating the method of service and the identity of the person with whom the charging letter was left. The certificate of service shall be filed with the administrative law judge.

(c) *Date.* The date of service of notice of the issuance of a charging letter instituting an administrative enforcement proceeding, or service of notice of the issuance of a supplement or amendment to a charging letter, is the date of its delivery, or of its attempted delivery if delivery is refused.

§ 280.606 Representation.

A respondent individual may appear and participate in person, a corporation by a duly authorized officer or employee, and a partnership by a partner. If a respondent is represented by counsel, counsel shall be a member in good standing of the bar of any State, Commonwealth or Territory of the United States, or of the District of Columbia, or be licensed to practice law in the country in which counsel resides if not the United States. A respondent personally, or through counsel or other representative who has the power of attorney to represent the respondent, shall file a notice of appearance with the administrative law judge. The Department will be represented by the Office of Chief Counsel for Export Administration, U.S. Department of Commerce.

§ 280.607 Filing and service of papers other than charging letter.

(a) *Filing.* All papers to be filed shall be addressed to ''FQA Administrative Enforcement Proceedings,'' at the address set forth in the charging letter, or such other place as the administrative law judge may designate. Filing by United States mail, first class postage prepaid, by express or equivalent parcel delivery service, or by hand delivery, is acceptable. Filing by mail from a foreign country shall be by airmail. In addition, the administrative law judge may authorize filing of papers by facsimile or other electronic means, provided that a hard copy of any such paper is subsequently filed. A copy of each paper filed shall be simultaneously served on each party.

(b) *Service.* Service shall be made by personal delivery or by mailing one copy of each paper to each party in the proceeding. Service by delivery service or facsimile, in the manner set forth in paragraph (a) of this section, is acceptable. Service on the Department shall be addressed to the Chief Counsel for Export Administration, Room H–3839, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC. 20230. Service on a respondent shall be to the address to which the charging letter was sent or to such other address as respondent may provide. When a party has appeared by counsel or other representative, service on counsel or other representative shall constitute service on that party.

(c) *Date.* The date of filing or service is the day when the papers are deposited in the mail or are delivered in person, by delivery service, or by facsimile.

(d) *Certificate of service.* A certificate of service signed by the party making service, stating the date and manner of service, shall accompany every paper, other than the charging letter, filed and served on parties.

(e) *Computing period of time.* In computing any period of time prescribed or allowed by this part or by order of the administrative law judge or the Under Secretary, the day of the act, event, or default from which the designated period of time begins to run is not to be included. The last day of the period so computed is to be included unless it is a Saturday, a Sunday, or a legal holiday (as defined in Rule 6(a) of the Federal Rules of Civil Procedure), in which case the period runs until the end of the next day which is neither a Saturday, a Sunday, nor a legal holiday. Intermediate Saturdays, Sundays, and legal holidays are excluded from the computation when the period of time prescribed or allowed is seven days or less.

§ 280.608 Answer and demand for hearing.

(a) *When to answer.* The respondent must answer the charging letter within 30 days after being served with notice of the issuance of a charging letter instituting an administrative enforcement proceeding, or within 30 days of notice of any supplement or amendment to a charging letter, unless time is extended under § 280.618 of this part.

(b) *Contents of answer.* The answer must be responsive to the charging letter and must fully set forth the nature of the respondent's defense or defenses. The answer must admit or deny specifically each separate allegation of the charging letter; if the respondent is without knowledge, the answer must so state and will operate as a denial. Failure to deny or controvert a particular allegation will be deemed an admission of that allegation. The answer must also set forth any additional or new matter the respondent believes supports a defense or claim of mitigation. Any defense or partial defense not specifically set forth in the answer shall be deemed waived, and evidence thereon may be refused, except for good cause shown.

(c) *Demand for hearing.* If the respondent desires a hearing, a written demand for one must be submitted with the answer. Any demand by the Department for a hearing must be filed with the administrative law judge within 30 days after service of the answer. Failure to make a timely written demand for a hearing shall be deemed a waiver of the party's right to a hearing, except for good cause shown. If no party demands a hearing, the matter will go forward in accordance with the procedures set forth in § 280.617 of this part.

(d) *English language required.* The answer, all other papers, and all documentary evidence must be submitted in English, or translations into English must be filed and served at the same time.

§ 280.609 Default.

(a) *General.* Failure of the respondent to file an answer within the time provided constitutes a waiver of the respondent's right to appear and contest the allegations in the charging letter. In such event, the administrative law judge, on the Department's motion and without further notice to the respondent, shall find the facts to be as alleged in the charging letter and render an initial decision containing findings of fact and appropriate conclusions of law and issue an initial decision and order imposing appropriate sanctions. The decision and order may be appealed to the Under Secretary in accordance with the applicable procedures set forth in § 280.623 of this part.

(b) *Petition to set aside default*—(1) *Procedure.* Upon petition filed by a respondent against whom a default order has been issued, which petition is accompanied by an answer meeting the requirements of 280.608(b) of this part, the Under Secretary may, after giving all parties an opportunity to comment, and for good cause shown, set aside the default and vacate the order entered thereon and remand the matter to the administrative law judge for further proceedings.

(2) *Time limits.* A petition under this section must be made within one year of the date of entry of the order which the petition seeks to have vacated.

§ 280.610 Summary decision.

At any time after a proceeding has been initiated, a party may move for a summary decision disposing of some or all of the issues. The administrative law judge may render an initial decision and issue an order if the entire record shows, as to the issue(s) under consideration:

(a) That there is no genuine issue as to any material fact; and

(b) That the moving party is entitled to a summary decision as a matter of law.

§ 280.611 Discovery.

(a) *General.* The parties are encouraged to engage in voluntary discovery regarding any matter, not privileged, which is relevant to the subject matter of the pending proceeding. The provisions of the Federal Rules of Civil Procedure relating to discovery apply to the extent consistent with this part and except as otherwise provided by the administrative law judge or by waiver or agreement of the parties. The administrative law judge may make

any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense. These orders may include limitations on the scope, method, time and place of discovery, and provisions for protecting the confidentiality of classified or otherwise sensitive information.

(b) *Interrogatories and requests for admission or production of documents.* A party may serve on any party interrogatories, requests for admission, or requests for production of documents for inspection and copying, and a party concerned may apply to the administrative law judge for such enforcement or protective order as that party deems warranted with respect to such discovery. The service of a discovery request shall be made at least 20 days before the scheduled date of the hearing unless the administrative law judge specifies a shorter time period. Copies of interrogatories, requests for admission and requests for production of documents and responses thereto shall be served on all parties, and a copy of the certificate of service shall be filed with the administrative law judge. Matters of fact or law of which admission is requested shall be deemed admitted unless, within a period designated in the request (at least 10 days after service, or within such additional time as the administrative law judge may allow), the party to whom the request is directed serves upon the requesting party a sworn statement either denying specifically the matters of which admission is requested or setting forth in detail the reasons why the party to whom the request is directed cannot truthfully either admit or deny such matters.

(c) *Depositions.* Upon application of a party and for good cause shown, the administrative law judge may order the taking of the testimony of any person by deposition and the production of specified documents or materials by the person at the deposition. The application shall state the purpose of the deposition and set forth the facts sought to be established through the deposition.

(d) *Enforcement.* The administrative law judge may order a party to answer designated questions, to produce specified documents or things or to take any other action in response to a proper discovery request. If a party does not comply with such an order, the administrative law judge may make a determination or enter any order in the proceeding as the ALJ deems reasonable and appropriate. The ALJ may strike related charges or defenses in whole or in part or may take particular facts relating to the discovery request to which the party failed or refused to respond as being established for purposes of the proceeding in accordance with the contentions of the party seeking discovery. In addition, enforcement by a district court of the United States may be sought under section 9(b)(6) of the Act.

§ 280.612 Subpoenas.

(a) *Issuance.* Upon the application of any party, supported by a satisfactory showing that there is substantial reason to believe that the evidence would not otherwise be available, the administrative law judge may issue subpoenas requiring the attendance and testimony of witnesses and the production of such books, records or other documentary or physical evidence for the purpose of the hearing, as the ALJ deems relevant and material to the proceedings, and reasonable in scope. Witnesses summoned shall be paid the same fees and mileage that are paid to witnesses in the courts of the United States. In case of contempt or refusal to obey a subpoena served upon any person pursuant to this paragraph, the district court of the United States for any district in which such person is found, resides, or transacts business, upon application by the United States and after notice to such person, shall have jurisdiction to issue an order requiring such person to appear and give testimony before the administrative law judge or to appear and produce documents before the administrative law judge, or both, and any failure to obey such order of the court may be punished by such court as contempt thereof.

(b) *Service.* Subpoenas issued by the administrative law judge may be served in any of the methods set forth in § 280.607(b) of this part.

(c) *Timing.* Applications for subpoenas must be submitted at least 10 days before the scheduled hearing or deposition, unless the administrative law judge determines, for good cause shown, that extraordinary circumstances warrant a shorter time.

§ 280.613 Matter protected against disclosure.

(a) *Protective measures.* The administrative law judge may limit discovery or introduction of evidence or issue such protective or other orders as in the ALJ's judgment may be needed to prevent undue disclosure of classified or sensitive documents or information. Where the administrative law judge determines that documents containing the classified or sensitive matter need to be made available to a party to avoid prejudice, the ALJ may direct that an unclassified and/or nonsensitive summary or extract of the documents be prepared. The administrative law judge may compare the extract or summary with the original to ensure that it is supported by the source document and that it omits only so much as must remain undisclosed. The summary or extract may be admitted as evidence in the record.

(b) *Arrangements for access.* If the administrative law judge determines that this procedure is unsatisfactory and that classified or otherwise sensitive matter must form part of the record in order to avoid prejudice to a party, the administrative law judge may provide the parties an opportunity to make arrangements that permit a party or a representative to have access to such matter without compromising sensitive information. Such arrangements may include obtaining security clearances or giving counsel for a party access to sensitive information and documents subject to assurances against further disclosure, including a protective order, if necessary.

§ 280.614 Prehearing conference.

(a) The administrative law judge, on his or her own motion or on request of a party, may direct the parties to participate in a prehearing conference, either in person or by telephone, to consider:

(1) Simplification of issues;

(2) The necessity or desirability of amendments to pleadings;

(3) Obtaining stipulations of fact and of documents to avoid unnecessary proof; or

(4) Such other matters as may expedite the disposition of the proceedings.

(b) The administrative law judge may order the conference proceedings to be recorded electronically or taken by a reporter, transcribed and filed with the ALJ.

(c) If a prehearing conference is impracticable, the administrative law judge may direct the parties to correspond with the ALJ to achieve the purposes of such a conference.

(d) The administrative law judge will prepare a summary of any actions agreed on or taken pursuant to this section. The summary will include any written stipulations or agreements made by the parties.

§ 280.615 Hearings.

(a) *Scheduling.* The administrative law judge, by agreement with the parties or upon notice to all parties of not less than 30 days, will schedule a hearing. All hearings will be held in Washington, DC., unless the administrative law judge determines, for good cause shown, that another location would better serve the interests of justice.

(b) *Hearing procedure.* Hearings will be conducted in a fair and impartial manner by the administrative law judge, who may limit attendance at any hearing or portion thereof to the parties, their representatives and witnesses if the administrative law judge deems this necessary or advisable in order to protect sensitive matter (see § 280.613 of this part) from improper disclosure. The rules of evidence prevailing in courts of law do not apply, and all evidentiary material deemed by the administrative law judge to be relevant and material to the proceeding and not unduly repetitious will be received and given appropriate weight.

(c) *Testimony and record.* Witnesses will testify under oath or affirmation. A verbatim record of the hearing and of any other oral proceedings will be taken by reporter or by electronic recording, transcribed and filed with the administrative law judge. A respondent may examine the transcript and may

obtain a copy by paying any applicable costs. Upon such terms as the administrative law judge deems just, the ALJ may direct that the testimony of any person be taken by deposition and may admit an affidavit or declaration as evidence, provided that any affidavits or declarations have been filed and served on the parties sufficiently in advance of the hearing to permit a party to file and serve an objection thereto on the grounds that it is necessary that the affiant or declarant testify at the hearing and be subject to cross-examination.

(d) *Failure to appear.* If a party fails to appear in person or by counsel at a scheduled hearing, the hearing may nevertheless proceed, and that party's failure to appear will not affect the validity of the hearing or any proceedings or action taken thereafter.

§ 280.616 Interlocutory review of rulings.

(a) At the request of a party, or on the administrative law judge's own initiative, the administrative law judge may certify to the Under Secretary for review a ruling that does not finally dispose of a proceeding, if the administrative law judge determines that immediate review may hasten or facilitate the final disposition of the matter.

(b) Upon certification to the Under Secretary of the interlocutory ruling for review, the parties will have 10 days to file and serve briefs stating their positions, and five days to file and serve replies, following which the Under Secretary will decide the matter promptly.

§ 280.617 Proceeding without a hearing.

If the parties have waived a hearing, the case will be decided on the record by the administrative law judge. Proceeding without a hearing does not relieve the parties from the necessity of proving the facts supporting their charges or defenses. Affidavits or declarations, depositions, admissions, answers to interrogatories and stipulations may supplement other documentary evidence in the record. The administrative law judge will give each party reasonable opportunity to file rebuttal evidence.

§ 280.618 Procedural stipulations; extension of time.

(a) *Procedural stipulations.* Unless otherwise ordered, a written stipulation agreed to by all parties and filed with the administrative law judge will modify any procedures established by this part.

(b) *Extension of time.* (1) The parties may extend any applicable time limitation, by stipulation filed with the administrative law judge before the time limitation expires.

(2) The administrative law judge may, on the judge's own initiative or upon application by any party, either before or after the expiration of any applicable time limitation, extend the time within which to file and serve an answer to a charging letter or do any other act required by this part.

§ 280.619 Decision of the administrative law judge.

(a) *Predecisional matters.* Except for default proceedings under § 280.609 of this part, the administrative law judge will give the parties reasonable opportunity to submit the following, which will be made a part of the record:

(1) Exceptions to any ruling by the judge or to the admissibility of evidence proffered at the hearing;

(2) Proposed findings of fact and conclusions of law;

(3) Supporting legal arguments for the exceptions and proposed findings and conclusions submitted; and

(4) A proposed order.

(b) *Decision and order.* After considering the entire record in the proceeding, the administrative law judge will issue a written initial decision. The decision will include findings of fact, conclusions of law, and findings as to whether there has been a violation of the Act, this part, or any order issued thereunder. If the administrative law judge finds that the evidence of record is insufficient to sustain a finding that a violation has occurred with respect to one or more charges, the ALJ shall order dismissal of the charges in whole or in part, as appropriate. If the administrative law judge finds that one or more violations have been committed, the ALJ may issue an order imposing administrative sanctions, as provided in this part. The decision and order

shall be served on each party, and shall become effective as the final decision of the Department 30 days after service, unless an appeal is filed in accordance with §280.623 of this part. In determining the amount of any civil penalty the ALJ shall consider the nature, circumstances and gravity of the violation and, with respect to the person found to have committed the violation, the degree of culpability, any history of prior violations, the effect on ability to continue to do business, any good faith attempt to achieve compliance, ability to pay the penalty, and such other matters as justice may require.

(c) *Suspension of sanctions.* Any order imposing administrative sanctions may provide for the suspension of the sanction imposed, in whole or in part and on such terms of probation or other conditions as the administrative law judge or the Under Secretary may specify. Any suspension order may be modified or revoked by the signing official upon application by the Department showing a violation of the probationary terms or other conditions, after service on the respondent of notice of the application in accordance with the service provisions of §280.607 of this part, and with such opportunity for response as the responsible signing official in his/her discretion may allow. A copy of any order modifying or revoking the suspension shall also be served on the respondent in accordance with the provisions of §280.607 of this part.

§ 280.620 Settlement.

(a) *Cases may be settled before service of a charging letter.* In cases in which settlement is reached before service of a charging letter, a proposed charging letter will be prepared, and a settlement proposal consisting of a settlement agreement and order will be submitted to the Assistant Secretary for approval and signature. If the Assistant Secretary does not approve the proposal, he/she will notify the parties and the case will proceed as though no settlement proposal had been made. If the Assistant Secretary approves the proposal, he/she will issue an appropriate order, and no action will be required by the administrative law judge.

(b) *Cases may also be settled after service of a charging letter.* (1) If the case is pending before the administrative law judge, the ALJ shall stay the proceedings for a reasonable period of time, usually not to exceed 30 days, upon notification by the parties that they have entered into good faith settlement negotiations. The administrative law judge may, in his/her discretion, grant additional stays. If settlement is reached, a proposal will be submitted to the Assistant Secretary for approval and signature. If the Assistant Secretary approves the proposal, he/she will issue an appropriate order, and notify the administrative law judge that the case is withdrawn from adjudication. If the Assistant Secretary does not approve the proposal, he/she will notify the parties and the case will proceed to adjudication by the administrative law judge as though no settlement proposal had been made.

(2) If the case is pending before the Under Secretary under §280.623 of this part, the parties may submit a settlement proposal to the Under Secretary for approval and signature. If the Under Secretary approves the proposal, he/she will issue an appropriate order. If the Under Secretary does not approve the proposal, the case will proceed to final decision in accordance with Section 280.623 of this part, as appropriate.

(c) Any order disposing of a case by settlement may suspend the administrative sanction imposed, in whole or in part, on such terms of probation or other conditions as the signing official may specify. Any such suspension may be modified or revoked by the signing official, in accordance with the procedures set forth in §280.619(c) of this part.

(d) Any respondent who agrees to an order imposing any administrative sanction does so solely for the purpose of resolving the claims in the administrative enforcement proceeding brought under this part. This reflects the fact that the Department has neither the authority nor the responsibility for instituting, conducting, settling, or otherwise disposing of criminal proceedings. That authority and responsibility is vested in the Attorney General and the Department of Justice.

(e) Cases that are settled may not be reopened or appealed.

§ 280.621 Reopening.

The respondent may petition the administrative law judge within one year of the date of the final decision, except where the decision arises from a default judgment or from a settlement, to reopen an administrative enforcement proceeding to receive any relevant and material evidence which was unknown or unobtainable at the time the proceeding was held. The petition must include a summary of such evidence, the reasons why it is deemed relevant and material, and the reasons why it could not have been presented at the time the proceedings were held. The administrative law judge will grant or deny the petition after providing other parties reasonable opportunity to comment. If the proceeding is reopened, the administrative law judge may make such arrangements as the ALJ deems appropriate for receiving the new evidence and completing the record. The administrative law judge will then issue a new initial decision and order, and the case will proceed to final decision and order in accordance with § 280.623 of this part.

§ 280.622 Record for decision and availability of documents.

(a) *General.* The transcript of hearings, exhibits, rulings, orders, all papers and requests filed in the proceedings and, for purposes of any appeal under § 280.623 of this part, the decision of the administrative law judge and such submissions as are provided for by § 280.623 of this part, will constitute the record and the exclusive basis for decision. When a case is settled after the service of a charging letter, the record will consist of any and all of the foregoing, as well as the settlement agreement and the order. When a case is settled before service of a charging letter, the record will consist of the proposed charging letter, the settlement agreement and the order.

(b) *Restricted access.* On the administrative law judge's own motion, or on the motion of any party, the administrative law judge may direct that there be a restricted access portion of the record for any material in the record to which public access is restricted by law or by the terms of a protective order entered in the proceedings. A party seeking to restrict access to any portion of the record is responsible for submitting, at the time specified in § 280.622(c)(2) of this part, a version of the document proposed for public availability that reflects the requested deletion. The restricted access portion of the record will be placed in a separate file and the file will be clearly marked to avoid improper disclosure and to identify it as a portion of the official record in the proceedings. The administrative law judge may act at any time to permit material that becomes declassified or unrestricted through passage of time to be transferred to the unrestricted access portion of the record.

(c) *Availability of documents*—(1) *Scope.* All charging letters, answers, initial decisions, and orders disposing of a case will be made available for public inspection in the BXA Freedom of Information Records Inspection Facility, U.S. Department of Commerce, Room H–6624, 14th Street and Pennsylvania Avenue, NW, Washington, DC 20230. The complete record for decision, as defined in paragraphs (a) and (b) of this section will be made available on request.

(2) *Timing.* Documents are available immediately upon filing, except for any portion of the record for which a request for segregation is made. Parties that seek to restrict access to any portion of the record under paragraph (b) of this section must make such a request, together with the reasons supporting the claim of confidentiality, simultaneously with the submission of material for the record.

§ 280.623 Appeals.

(a) *Grounds.* A party may appeal to the Under Secretary from an order disposing of a proceeding or an order denying a petition to set aside a default or a petition for reopening, on the grounds:

(1) That a necessary finding of fact is omitted, erroneous or unsupported by substantial evidence of record;

(2) That a necessary legal conclusion or finding is contrary to law;

(3) That prejudicial procedural error occurred; or

(4) That the decision or the extent of sanctions is arbitrary, capricious or an abuse of discretion. The appeal must specify the grounds on which the appeal is based and the provisions of the order from which the appeal is taken.

(b) *Filing of appeal.* An appeal from an order must be filed with the Office of the Under Secretary for Export Administration, Bureau of Export Administration, U.S. Department of Commerce, Room H–3898, 14th Street and Constitution Avenue, NW., Washington, DC 20230, within 30 days after service of the order appealed from. If the Under Secretary cannot act on an appeal for any reason, the Under Secretary will designate another Department of Commerce official to receive and act on the appeal.

(c) *Effect of appeal.* The filing of an appeal shall not stay the operation of any order, unless the order by its express terms so provides or unless the Under Secretary, upon application by a party and with opportunity for response, grants a stay.

(d) *Appeal procedure.* The Under Secretary normally will not hold hearings or entertain oral argument on appeals. A full written statement in support of the appeal must be filed with the appeal and be simultaneously served on all parties, who shall have 30 days from service to file a reply. At his/her discretion, the Under Secretary may accept new submissions, but will not ordinarily accept those submissions filed more than 30 days after the filing of the reply to the appellant's first submission.

(e) *Decisions.* The decision will be in writing and will be accompanied by an order signed by the Under Secretary giving effect to the decision. The order may either dispose of the case by affirming, modifying or reversing the order of the administrative law judge or may refer the case back to the administrative law judge for further proceedings.

(f) *Delivery.* The final decision and implementing order shall be served on the parties and will be publicly available in accordance with § 280.622 of this part.

(g) *Judicial review.* The charged party may appeal the Under Secretary's written order within 30 days to the appropriate United States District Court pursuant to section 9(b)(3) of the Act (15 U.S.C. 5408(b)(3)) by filing a notice of appeal in such court within 30 days from the date of such order and by simultaneously sending a copy of such notice by certified mail to the Chief Counsel for Export Administration, Room H–3839, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230. The findings and order of the Under Secretary shall be set aside by such court if they are found to be unsupported by substantial evidence, as provided in section 706(2) of title 5 United States Code.

Subpart H—Recordal of Insignia

§ 280.700 Recorded insignia required prior to offer for sale.

(a) Any manufacturer or private label distributor of a fastener must, prior to any sale or offer for sale of any fastener which is required by the standards and specifications by which it is manufactured to bear a raised or depressed insignia identifying its manufacturer or private label distributor, apply for and record an insignia to be applied to any fastener which is to be sold or offered for sale to ensure that each fastener may be traced to its manufacturer or private label distributor.

(b) The manufacturer's or private label distributor's insignia must be applied to any fastener which is sold or offered for sale if such fastener is required by the standards and specification by which it is manufactured to bear a raised or depressed insignia identifying its manufacturer or private label distributor. If the fastener has no head, the insignia must be applied to another surface area in a legible manner.

(c) The insignia must be applied through a raised or depressed impression. The insignia must be readable with no greater than 10x magnification.

THE WRITTEN APPLICATION

§280.710 Applications for insignia.

(a) Each manufacturer or private label distributor must submit a written application for recordal of an insignia on the Fastener Insignia Register along with the prescribed fee. The application must be in a form prescribed by the Commissioner.

(b) The written application must be in the English language and must include the following:

(1) The name of the applicant;

(2) The address of the applicant;

(3) The entity, domicile, and state of incorporation, if applicable, of the applicant;

(4) Either:

(i) A request for recordal and issuance of a unique alphanumeric designation by the Commissioner, or

(ii) A request for recordal of a trademark, which is the subject of either a duly filed application or a registration for fasteners in the name of the applicant in the U.S. Patent and Trademark Office on the Principal Register, indicating the application serial number or registration number and accompanied by a copy of the drawing page of the application or a copy of the registration;

(5) A statement that the applicant will comply with the applicable provisions of the Fastener Quality Act;

(6) A statement that the person signing the application on behalf of the applicant has personal knowledge of the facts relevant to the application and that the person possesses the authority to act on behalf of the applicant;

(7) A verification stating that the person signing declares under penalty of perjury under the laws of the United States of America that the information and statements included in the application are true and correct; and

(8) The application fee.

(c) An applicant may designate only one registered trademark for recordal on the Fastener Insignia Register in a single application. The trademark application or registration which forms the basis for the fastener recordal must be in active status, that is a pending application or a registration which is not expired, abandoned or canceled, at the time of the application for recordal.

(d) Applications and other documents should be addressed to: Box Fastener, Commissioner of Patents and Trademarks, Washington DC 20231.

§280.711 Review of the application.

The Commissioner will review the application for compliance with §280.710. If the application does not contain one or more of the elements required by §280.710, the Commissioner will not issue a certificate of recordal, and will return the papers and fees. The Commissioner will notify the applicant of any defect in the application. Applications for recordal of an insignia may be re-submitted to the Commissioner at any time.

§280.712 Certificate of recordal.

If the application complies with the requirements of §280.710, the Commissioner shall accept the application and issue a certificate of recordal. Such certificate shall be issued in the name of the United States of America, under the seal of the Patent and Trademark Office, and a record shall be kept in the Patent and Trademark Office. The certificate of recordal shall display the recorded insignia of the applicant, and state the name, address, legal entity and domicile of the applicant, as well as the date of issuance of such certificate.

§280.713 Recordal of additional insignia.

(a) A manufacturer or private label distributor to whom the Commissioner has issued an alphanumeric designation may apply for recordal of its trademark for fasteners if the trademark is the subject of a duly filed application or is registered in the U.S. Patent and Trademark Office on the Principal Register. Upon recordal, either the alphanumeric designation or the registered mark, or both, may be used as recorded insignias.

(b) A manufacturer or private label distributor for whom the Commissioner has recorded a trademark as its fastener insignia, may apply for issuance and recordal of an alphanumeric designation as a fastener insignia. Upon

recordal, either the alphanumeric designation or the trademark, or both, may be used as recorded insignias.

POST-RECORDAL MAINTENANCE

§ 280.720 Maintenance of the certificate of recordal.

(a) Certificates of recordal remain in an active status for five years and may be maintained in an active status for five-year periods running consecutively from the date of issuance of the certificate of recordal upon compliance with the requirements of § 280.720(c).

(b) Maintenance applications shall be required only if the holder of the certificate of recordal is a manufacturer or private label distributor at the time the maintenance application is required.

(c) Certificates of recordal will be designated as inactive unless, within six months prior to the expiration of each five-year period running consecutively from the date of issuance, the certificate holder files the prescribed maintenance fee and the maintenance application. The maintenance application must be in the English language and must include the following:

(1) The name of the applicant;

(2) The address of the applicant;

(3) The entity, domicile, and state of incorporation, if applicable, of the applicant;

(4) A copy of applicant's certificate of recordal;

(5) A statement that the applicant will comply with the applicable provisions of the Fastener Quality Act;

(6) A statement that the person signing the application on behalf of the applicant has knowledge of the facts relevant to the application and that the person possesses the authority to act on behalf of the applicant;

(7) A verification stating that the person signing declares under penalty of perjury under the laws of the United States of America that the information and statements included in the application are true and correct; and

(8) The maintenance application fee.

(d) Where no maintenance application is timely filed, a certificate of recordal will be designated inactive. However, such certificate may be designated active if the certificate holder files the prescribed maintenance fee and application and the additional surcharge within six months following the expiration of the certificate of recordal.

(e) After the six-month period following the expiration of the certificate of recordal, the certificate of recordal shall be deemed active only if the certificate holder files a new application for recordal with the prescribed fee for obtaining a fastener insignia and attaches a copy of the expired certificate of recordal.

(f) A separate maintenance application and fee must be filed and paid for each recorded insignia.

§ 280.721 Notification of changes of address.

The applicant or the holder of a certificate of recordal shall notify the Commissioner of any change of address or change of name no later than six months after the change. The holder must do so whether the certificate of recordal is in an active or inactive status.

§ 280.722 Transfer or amendment of the certificate of recordal.

(a) The certificate of recordal cannot be transferred or assigned.

(b) The certificate of recordal may be amended only to show a change of name or change of address.

§ 280.723 Transfer or assignment of the trademark registration or recorded insignia.

(a) A trademark application or registration which forms the basis of a fastener recordal may be transferred or assigned. Any transfer or assignment of such an application or registration shall be recorded in the Patent and Trademark Office within three months of the transfer or assignment. A copy of such transfer or assignment must also be sent to: Box Fastener, Commissioner of Patents and Trademarks, Washington, DC 20231.

(b) Upon transfer or assignment of a trademark application or registration which forms the basis of a certificate of recordal, the Commissioner shall designate the certificate of recordal as inactive. The certificate of recordal shall be deemed inactive as of the effective

date of the transfer or assignment. Certificates of recordal designated inactive due to transfer or assignment of a trademark application or registration cannot be reactivated.

(c) An assigned trademark application or registration may form the basis for a new application for recordal of a fastener insignia.

(d) A fastener insignia consisting of an alphanumeric designation issued by the Commissioner can be transferred or assigned.

(e) Upon transfer or assignment of an alphanumeric designation, the Commissioner shall designate such alphanumeric designation as inactive. The alphanumeric designation shall be deemed inactive as of the effective date of the transfer or assignment. Alphanumeric designations which are designated inactive due to transfer or assignment may be reactivated upon application by the assignee of such alphanumeric designation. Such application must meet all the requirements of §280.710 and must include a copy of the pertinent portions of the document assigning rights in the alphanumeric designation. Such application must be filed within six months of the date of assignment.

§280.724 Change in status of trademark registration or amendment of the trademark.

(a) The Commissioner shall designate the certificate of recordal as inactive, upon:

(1) Issuance of a final decision on appeal which refuses registration of the application which formed the basis for the certificate of recordal; or

(2) Abandonment of the application which formed the basis for the certificate of recordal; or

(3) Cancellation or expiration of the trademark registration which formed the basis of the certificate of recordal.

(b) Any amendment of the mark in a trademark application or registration which forms the basis for a certificate of recordal will result in such certificate of recordal being designated inactive. The certificate of recordal shall become inactive as of the date of the amendment of the trademark. A new application for recordal of the amended trademark application or registration may be submitted to the Commissioner at any time.

(c) Certificates of recordal designated inactive due to cancellation, expiration, abandonment or amendment of the trademark application or registration cannot be reactivated.

§280.725 Cumulative listing of recordal information.

The Commissioner shall maintain a record of the names, current addresses, and legal entities of all recorded manufacturers and private label distributors and their recorded insignia.

§280.726 Records and files of the Patent and Trademark Office.

The records relating to fastener insignia shall be open to public inspection. Copies of any such records may be obtained upon request and payment of the fee set by the Commissioner.

PART 285—NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM

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